



Office Of Health Care Access Certificate of Need Application

Final Decision

Applicant: Robert D. Russo, M.D. & Associates Radiology, P.C.

Docket Number: 04-30252-CON

Project Title: Acquisition of a fixed PET/CT unit in Bridgeport

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

Filing Date: March 16, 2005

Hearing Date: May 12, 2005

Presiding Officer: Cristine A. Vogel

Intervenors: St. Vincent's Medical Center
Bridgeport Hospital

Decision Date: June 10, 2005

Default Date: June 14, 2005

Project Description: Robert D. Russo, M.D. & Associates Radiology, P.C. ("Applicant") proposes to acquire a fixed positron emission tomography/computed tomography ("PET/CT") scanner for its 2660 Main Street Bridgeport practice location. The proposal has a total capital cost of \$2,302,392.

Nature of Proceedings: On March 16, 2005, the Office of Health Care Access ("OHCA") received a completed Certificate of Need ("CON") application from Robert D. Russo, M.D. & Associates Radiology, P.C. ("Applicant") proposing to acquire a fixed positron emission tomography/computed tomography ("PET/CT") scanner for its 2660 Main Street Bridgeport practice location. The proposal has a total capital cost of \$2,302,392.

A notice to the public regarding OHCA's receipt of the Applicant's Letter of Intent was published in *The Connecticut Post* (Bridgeport) on February 28, 2004. OHCA received a request on April 8, 2004 from the Chairperson of the Fairfield County Mobile PET Collaborative requesting that a hearing be held on the Applicant's CON application. The Collaborative was at that time comprised of Bridgeport Hospital, Danbury Hospital, Greenwich Hospital, Norwalk Hospital, St. Vincent's Medical Center and Stamford Hospital.

A public hearing regarding the CON application was held on May 12, 2005. The Applicant was notified of the date, time and place of the hearing, and a notice to the public was published in *The Connecticut Post* on April 9, 2005. Commissioner Cristine A. Vogel served as Presiding Officer for this case. The public 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 C.G.S. Section 19a-639.

St. Vincent's Medical Center ("SVMC") petitioned for intervenor status in the proceeding. The Presiding Officer granted SVMC's request for intervenor status with the right to present evidence and argument, as well as the right to cross-examine witnesses for the Applicant on the issues raised in its petition.

Bridgeport Hospital ("BH") petitioned for intervenor status in the proceeding. The Presiding Officer granted BH's request for intervenor status with the right to present evidence and argument, as well as the right to cross-examine witnesses for the Applicant on the issues raised in its petition.

The Presiding Officer heard testimony from the Applicant and Intervenors and, in rendering this decision, considered the entire record of the proceeding. OHCA's authority to review and approve, modify or deny the CON application 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 of the Proposal on the Applicant'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. Robert D. Russo, M.D. & Associates, Radiology, P.C. ("Applicant" or "P.C.") is a for-profit professional corporation which operates a multi-site private radiology practice in Fairfield County. The president and owner of the P.C. is Robert D. Russo, M.D. The Applicant's practice currently has eleven radiologists and one physician assistant. .
(February 17, 2004 Letter of Intent, page 3, July 16, 2004 CON application, pages 1 and 10 and March 16, 2005 completeness responses, page 15)

2. The Applicant proposes to acquire a PET/CT Scanner for its 2660 Main Street Bridgeport practice location.¹ (*July 16, 2004 CON application, cover letter and Exhibits 15 and 16*)
3. The Applicant previously received authorization from OHCA under Docket Number 02-556, as modified by Docket Number 05-22929-MDF, to acquire a replacement CT scanner for this practice location. The authorized acquisition of the replacement CT scanner has not been implemented as yet. The Applicant indicates that the proposal under Docket Number 04-30252-CON represents an upgrade to the CT scanner by adding PET capability and that the acquisition of a PET/CT unit will replace the existing CT scanner at this location. (*February 17, 2004 Letter of Intent, page 4, July 16, 2005 CON application, cover letter and March 16, 2005 Completeness Responses, Pages 2 and 7*)
4. The Applicant identifies the primary service area for the CON proposal as the towns of Ansonia, Bridgeport, Easton, Fairfield, Monroe, Norwalk, Seymour, Shelton, Stratford, Trumbull, Weston, Westport and Wilton. The Applicant identifies the secondary service area for the CON proposal as the towns of Darien, Milford, New Canaan, Ridgefield and Stamford. (*March 16, 2005 Completeness Responses, Page 3*)
5. The following entities currently provide PET or PET/CT services, have CON authorization, or a CON determination that no CON was required related to the provision of PET or PET/CT in the towns designated by the Applicant as it's service area:
 - a. Advanced Radiology Consultants, full-time fixed PET scanner in Trumbull.
 - b. Fairfield County Mobile PET Collaborative, part-time mobile PET scanner, authorized to upgrade to PET/CT.²
 - c. HealthCenter Imaging, Trumbull, Fixed full time PET/CT scanner for cardiac only.
 - d. Milford Hospital, Milford, part-time mobile PET scanner. (*OHCA Interrogatories, Page 2*)
6. The Hospitals making up the Fairfield County Mobile PET Collaborative (which presently includes) Bridgeport Hospital, St. Vincent's Medical Center, Norwalk Hospital, Stamford Hospital and Danbury Hospital currently provide PET scanning services on a mobile unit. These Hospitals have been authorized by OHCA to upgrade their mobile unit from a PET unit to a PET/CT modality, but have not yet instituted this authorized upgrade. (*Final Decision under Docket Number 02-556, as modified*)

¹ PET scanning is a diagnostic tool that involves the administration of a radiopharmaceutical agent with a positron emitting isotope and measures the distribution of that isotope to create images. PET/CT is a more recent imaging modality that combines PET and CT scanning into a single device and provides simultaneous structural and metabolic (biochemical) information. A radiopharmaceutical is a drug that contains radioactive atoms. (*July 16, 2004 CON application, page 26, CON application of the Fairfield County Mobile PET Collaborative under Docket Number 00-509, page 9, and Mosby's Medical Dictionary, Fifth Edition*)

² The Collaborative hospitals have not yet implemented this upgrade to PET/CT and the CON for that upgrade currently has a CON expiration date of August 6, 2005 by which time the Collaborative hospitals must fully implement the authorized project or it will lapse.

7. The Applicant based the need for the acquisition of the PET/CT scanner on the following factors:
 - a. Improvement in the quality of imaging services in the region;
 - b. Provision of full continuum of imaging services;
 - c. Loss of physician referrals;
 - d. Aging of the population, and

(July 16, 2004 CON application, pages 2-3 and March 16, 2005 completeness responses, pages 1-2, 4-5 and 9)
8. The Applicant asserts that none of the Bridgeport hospitals have fellowship-trained Nuclear Medicine radiologists. *(February 17, 2004 Letter of Intent, Page 5 and April 29, 2005 Response to Interrogatories, page 4)*
9. Tatiana S. Kain, M.D., a member of the P.C., is the lead radiologist and will read the majority of the PET and PET/CT scans. Dr. Kain is a fellowship trained Nuclear Medicine radiologist. The Applicant will maintain a fully qualified radiologist at all times to read these studies. The additional radiologists who will be reading the studies are Gioia J. Riccio, M.D., and Robert D. Russo, M.D and John P. Donahue, M.D. *(March 16, 2005 Completeness Responses Pages 16 and 17 and July 16, 2004 CON application, page 8)*
10. The Applicant's entire practice is accredited by JCAHO. The Applicant's mammography, ultrasound and MRI services are also accredited by the American College of Radiology. CT scanning services are currently in process of being accredited. *(July 16, 2004 CON application, pages 9 and 115 and March 16, 2005 Completeness Responses, page 16)*
11. The American College of Radiology does not require the presence of a fellowship-trained nuclear medicine radiologist in order to receive ACR accreditation. The Applicant indicates that referring physicians and third party payers radiology management companies would like this to be the community standard, however, this has not been documented. *(April 29, 2005 Response to Interrogatories, Page 9)*
12. The Applicant claims that it is disruptive to the patient's care if the CT scan is done within the Applicant's office and the PET scan is done at another location, and neither the PET provider nor the Applicant has access to the images for comparison and fusion needs. This claim has not been documented. *(March 16, 2005 Completeness Responses Pages 4-5)*
13. The Applicant claims that the inability to perform PET scans has adversely affected the practice in the following ways:
 - a. Referring physicians, and in particular neurologists and oncologists, are well aware of the complimentary nature of the sophisticated imaging modalities. Therefore, they do not use the Applicant's existing services because they know it is limited in the ability to perform PET. This claim has not been documented or verified.

- b. According to the Applicant, it is beneficial to have a CT scan, an ultrasound and MRI imaging on a patient and be able to merge PET scan data from the same source, or to consider it in the final diagnostic determination.
- c. The high degree of accuracy, speed and convenience of PET/CT has the potential of turning the modality into the standard of care for early detection of diseases.
- d. The Applicant estimates that the adverse financial impact of not being able to provide PET scanning would be the loss of up to 3,000 CT scans every year at a value of approximately \$900,000 per year. This estimate has not been quantified in a verifiable way.

(March 16, 2005 Completeness Responses, Pages 2- 4)

14. The Applicant’s practice modality mix at its various locations are as follows:

Table 1: Imaging Modality Mix at Practice Locations

	2660 Main Street Bridgeport	4699 Main Street Bridgeport	1261 Post Road Fairfield	111 East Avenue Norwalk	2595 Main Street Stratford	2909 Main Street Stratford	125 Kings Highway Westport
X-Ray	X	X	X	X			
Digital X-Ray			X				
X-Ray & Fluoroscopy	X	X	X	X		X	X
Ultrasound	X	X	X	X		X	X
CT	X						
Multi Slice CT		X	X	X		X	
Mammography	X					X	X
Digital Mammography		X	X	X			
CAD Mammography	X		X			X	X
Mammotome		X					
Nuclear Medicine	X						
Bone Densitometry	X	X		X		X	X
Open MRI				X			
High Field MRI					X		

(March 16, 2005 Completeness Responses, Page 22)

15. The Applicant indicates that its radiology practice continually monitors its referral patterns and requests that cannot be fulfilled. The Applicant claims that this monitoring has resulted in the following findings:

- a. The practice’s referring physicians often send their patients out of the area for PET scans.
- b. The referring physicians’ primary concern is the lack of nuclear trained professionals providing PET scans in the service area.
- c. The inability of the Applicant to perform PET services limits the ability to practice full service radiology and therefore, to complete the diagnostic workup on patients.
- d. The referring physicians, who rely on the Applicant in consultation, expect the Applicant to be able to perform PET scanning and fusion imaging, where the images from PET, CT and MRI as well as Ultrasound can be merged into a single diagnostic result. Presently, this process is incomplete. Without the PET component the Applicant is not able to perform these merges and fusion imaging. *(March 16, 2005 Completeness Responses, Page 1-2)*

16. The Applicant provided CY 2004 total visits for the two Bridgeport practice locations by town, as follows:

Table 3: CY 2004 diagnostic imaging visits for CY 2004 for Applicant’s Bridgeport sites:

Towns	2660 Main Street Bridgeport	4699 Main Street Bridgeport	Total for two locations
Bridgeport	16,114	12,566	28,680
Trumbull	1,113	6,180	7,293
Shelton	752	2,448	3,200
Fairfield	900	2,049	2,949
Monroe	469	2,022	2,491
Stratford	831	1,495	2,326
Milford	360	756	1,116
Easton	157	692	849
Other CT towns	<u>1,121</u>	<u>2,532</u>	<u>3,653</u>
TOTAL	21,817	30,740	52,557

(April 29, 2005 Response to Interrogatories, Page 3 and 4)

- 17. The Applicant performs 14,000 CT scans per year in its various practice locations. According to the Applicant, this number constitutes the highest outpatient CT volume for any radiology practice in the primary service area. *(April 29, 2005 Response to Interrogatories, Page 4)*
- 18. The Applicant indicates that the proposed PET/CT scanner will be for the Applicant’s entire practice and that the Bridgeport location is centrally located and is the most beneficial from a financial and logistical perspective. Patients who present in other practice locations that ultimately need PET imaging will be sent to the Bridgeport location. *(April 29, 2005 Response to Interrogatories, Page 2-3)*

19. The Applicant indicates that the need for PET is based on the aging of the Bridgeport population. In Bridgeport alone, the Applicant indicates that PET scanning volume is projected to increase by nearly 250% from 2003 – 2006³. The Applicant indicates that the diagnosis of cancer is expected to double in the next 50 years. In addition, with Medicare’s approval of Alzheimer’s screenings by PET, the neurological applications will increase as well. The Applicant has not demonstrated how any of these estimates are specifically used in the Applicant’s utilization projections for this project. *(March 16, 2005 Completeness Responses, Pages 5 and 9)*

20. The Applicant provides the following breakdown of percentage of patients at the Applicant’s two Bridgeport locations by age cohort:

	<u>2660 Main Street</u>	<u>4699 Main Street</u>
Age 0-44	26.6%	24.5%
Age 45 – 65	49.1%	46.1%
Age 66+	24.2%	29.3%

(April 29, 2005 Response to Interrogatories, Page 9)

21. The Applicant projects imaging studies on the proposed unit as follows:

Table 4: Proposed PET scan utilization for years one through three

Year One	Year Two	Year Three
250	375	500

This projection is based on historical requests for PET scans from referring physicians and the Applicant’s analysis of recent CT, Ultrasound and MRI volumes. These historical requests and analysis of practice volumes were not verified or documented by the Applicant. *(July 16, 2004 CON application, Pages 4 and 6)*

22. The Applicant provided utilization projections for the proposal specifically for CT scans, PET scans as well as PET/CT scans:

- a. The Applicant will use the requested equipment more for CT scans and PET scans than for combined PET/CT studies *((March 16, 2005 Completeness Responses, Page 5)*
- b. When asked by OHCA in OHCA’s interrogatories to provide the projected utilization for this project separately by PET, CT and PET/CT, the Applicant provides a quantification of 14,332 CTs for 2006 and 205 PET scans for 2006. The Applicant did not wish to project a PET/CT volume at that time as the Applicant indicated that its request is to be able to perform PET. It is unclear whether the 14,332 projected CT scans is for this unit alone or for the entire practice’s CT services. *(April 29, 2005 Response to OHCA Interrogatories, Page 6)*

³ The Applicant uses a projection provided by the Fairfield County Mobile PET Collaborative hospitals in their CON application for an upgrade from PET to PET/CT which was approved under Docket Number 02-584.

- c. In its revised prefile testimony, provided subsequent to the submission of prefile testimony by the Intervenor and just days before the public hearing, the Applicant provided a projection of the number estimated PET/CT scans. The Applicant estimates that 125 PET/CT scans will also be performed on the proposed unit. *(May 10, 2005 Revised Applicant Prefile, page 3)*
23. In order to arrive at its utilization projections, the Applicant indicates that it had taken the following steps:
- a. The Applicant analyzed a sampling of patient record from the Applicant's data base and found that 450 CT studies were referred back to the referring physician with a recommendation for a PET study.
 - b. The Applicant performed a further analysis of diagnostic versus therapeutic interventions, adjusted the number of PET scans due to the number of neoplasms and neurological conditions (which are conditions which would possibly require the use of a PET or PET/CT scan) to reach the additional 250 procedures in the first year.
 - c. Population growth and the increasing indications for use of PET for other conditions were also factored in as growth.
 - d. In addition to the above, interviews with neurological and oncological colleagues as to their increasing use of PET scans were also factored into years two and three.

The Applicant has not provided any supporting documentation regarding these data reports or the sampling of patient records. The Applicant has not indicated the size of the sample used and no calculation of this methodology has been provided to OHCA.

(March 16, 2005 completeness responses, page 13 and May 10, 2005 Revised Applicant Prefile, Page 4)

24. According to the Applicant, its internal analysis of MRI and CT studies show a doubling of its neurological volume in the last two years. These studies could be better visualized as PET/CTs. No analysis has been filed in the CON application so it cannot be verified by OHCA. *(March 16, 2005 completeness responses, page 12)*
25. The Applicant does not plan to do cardiac PET studies (MPI or Cardiac FDG). *(March 16, 2005 Completeness Responses, Page 9)*

26. The Applicant will enter into a contract with P.E.T. Net Pharmaceuticals Services, Inc. or other radiopharmaceutical provider for the purchase of F-18 FDG⁴. F-18 FDG will be used for a total body scan for evaluation of malignancy and tumor staging as well as for assessment of response to therapy. It will also be used for brain imaging in order to evaluate for Alzheimer's Disease, dementia and tumor. *(March 16, 2005 Completeness Responses, Pages 7-8)*
27. No radiopharmaceuticals will be produced by the Applicant. A Hot Lab is used as a holding and transfer station for the radiopharmaceuticals. *(March 16, 2005 Completeness Responses, Page 8)*
28. The Applicant asserts that the addition of the PET scanner should have no adverse impact on any other provider in Connecticut and that the addition of the proposed equipment will permit the current population served and proposed target population to obtain higher quality services as well as expanded procedures to this population. *(July 16, 2004 CON application, page 5)*
29. The Applicant asserts that its needs assessment has shown that the Hospitals' mobile unit is not meeting the need for PET services within the service area where the need continues to grow along with the aging population. This assertion has not been documented or verified. *(July 16, 2004 CON application, cover letter)*
30. The Applicant states that the current scheduling backlogs in Fairfield County range from 5 to 7 days in the service area. Due to the mobile nature of the Collaborative's unit, there are only limited days available for PET scans at each Collaborative Hospital site. *(March 16, 2005 Completeness Responses, Page 10 and April 29, 2005 Response to Interrogatories, Pages 4-5)*
31. SVMC states that it is generally able to schedule patients for PET scanning within one week. Dr. Kevin Dickey of SVMC stated that PET and PET/CT scanning are diagnostic procedures that are non-emergent and scheduling patients within a week is clinically appropriate and the Applicant did not contest this testimony at the hearing. *(May 9, 2005 Revised Prefile Testimony of Kevin Dickey, M.D., for SVMC)*
32. The Applicant asserts that area physicians have stated to the Applicant that they are referring patients out of the service area due to the lack of nuclear trained professionals in the area performing PET studies. This assertion has not been verified by the Applicant. The Applicant contends that the proposed CON doesn't affect the mobile PET providers in the region as the patients are leaving the region anyway, and the mobile units are serving the hospitals patient population and referral base, not the Applicant's. This contention has not been verified or documented. The Applicant indicates that any change in the volume numbers of the area hospitals will not place those providers in financial jeopardy as they pay for the mobile PET services on a per case basis. *(July 16, 2004 CON Application, Page 5 and March 16, 2005 Completeness Responses, Pages 10-11)*

⁴ F-18 FDG or Fluorodeoxyglucose is the most widely used PET radiotracer which aids in the interpretation of the detection of recurrent tumors and to distinguish between benign and malignant disease.

33. The Applicant indicates that the exclusive contracts the area hospitals have with their radiologists prevent the Applicant from performing PET/CT scans at the Hospitals. Therefore, the Applicant claims that it is the only radiologist practice in Fairfield County, without access to PET/CT. This has not been verified or documented by the Applicant. When asked by OHCA to provide a list of where all of the radiologists in the service area provide PET or PET/CT, the Applicant did not or was not able to provide such a list. *(July 16, 2004 CON Application, Page 5 and April 29, 2005 Response to Interrogatories)*
34. St. Vincent's Medical Center currently operates its mobile PET scanning service 10 hours per week and performed 368 scans in FY 2004, which is an average of 7.1 patients per week. *(Docket Number 00-509 Quarterly Utilization Reporting for FY 2004)*
35. Bridgeport Hospital currently operates its mobile PET scanning service approximately 10 hours per week and performed 194 scans in FY 2004, which is an average of 3.7 patients per week. *(Docket Number 00-509 Quarterly Utilization Reporting for FY 2004)*
36. Combined SVMC and BH performed 562 scans in FY 2004 at their two PET scanning locations. *(Docket Number 00-509 Quarterly Utilization Reporting for FY 2004)*
37. Medical Specialists of Fairfield LLC, an oncology physician practice based in Fairfield and Bridgeport, provided a letter signed by five of the practice's physician members, which states that they send patients "out for PET scanning". Black Rock Turnpike Medical Group, P.C., a hematology, oncology and internal medicine physician practice based in Trumbull, provided a letter signed by its three member physicians, which states that they have been sending patients out of the area for PET studies. The Applicant has not verified or documented how many of these patients may have been sent out of the region or the state for PET or PET/CT scanning, over what period of time and for what specific reasons. No physicians from either of these two physician groups testified at the public hearing. *(March 16, 2005 Completeness Responses, Pages 20 -21)*
38. SVMC testified to the following:
- a. SVMC testified that the radiologists who service SVMC patients, Fairfield County Radiology Associates, are capable of reading PET scans and oncologists, radiation oncologists and other specialists have been sending their patients to SVMC's PET services.
 - b. Dr. Kevin Dickey of SVMC testified that by definition, all radiologists who are certified by the American Board of Radiology are qualified to interpret nuclear medicine as well as other imaging studies. The Applicant did not contest this testimony.
 - c. SVMC provided documentation to demonstrate that every oncologist who signed the two letters of support for the Applicant's project (see Finding of Fact #37), have sent patients to SVMC for PET scanning in the past four months.

- d. The mobile PET scanning unit is currently available to SVMC for 10 hours per day for one day per week and this is the same for Bridgeport Hospital. SVMC indicates that, based on one day per week for 52 weeks per year, it can handle capacity growth to 520 scans per year before needing to increase the amount of days contracted for with the mobile scanner vendor. SVMC testifies that this calculation is based on an average of one patient being scanned per hour and the Applicant did not contest this testimony. In addition, Bridgeport Hospital has the same capacity of 520 scans per year. The mobile PET scanner is at SVMC on Fridays and Bridgeport Hospital on Mondays. Aggregating both hospitals' capacity, at one 10 hour day each per week, there could be capacity for 1040 scans annually between the two existing PET providers serving the Bridgeport area.

(May 9, 2005 Revised Prefile Testimony of St. Vincent's Medical Center, Page 2)

39. Bridgeport Hospital testified to the following:

- a. Dr. Charles I. Heller and Dr. Scott Charles Williams are both Board Certified in Nuclear Medicine. According to Bridgeport Hospital both have substantial experience reading PET scans.
- b. Between all of the Fairfield County Mobile PET Collaborative hospital providers, PET scanning is available almost every day of the week to residents of Fairfield County.
- c. Bridgeport Hospital states that it has received more than 40 referrals from Medical Specialists of Fairfield, LLC and Black Rock Turnpike Medical Group, P.C. Bridgeport Hospital has not indicated what time period this represents and has not provided specific documentation in this regard.

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

40. The proposed capital cost for this project is \$2,302,392, broken out by the following cost components:

Capital Lease of PET/CT	\$2,124,898
Renovation of space	\$ 50,000
Sales Tax on Equipment	<u>\$ 127,494</u>
Total	\$2,302,392

(March 16, 2005 completeness responses, page 66)

41. The Applicant will renovate the existing CT room to accommodate the PET/CT unit. *(July 16, 2004 CON Application, Page 11)*

42. Applicant has a contract draft with GE Healthcare Financial Services to the lease of the equipment (GEMS Discovery 8 slice PET/CT) at a financed equipment cost of \$2,124,898.40. *(July 16, 2004 CON application, Exhibit 17)*
43. The source of funding for renovations is operating funds. Applicant is entering into a capital lease arrangement for the PET/CT unit. *(July 16, 2004 CON Application, Page 13)*
44. The Applicant projects incremental revenue from operations for the project, as \$1,298 for year one, \$55,516 for year two and \$269,735 for year three. *(July 16, 2004 CON Application, Page 16)*
45. Current Payer Mix for the Applicant's entire practice is as follows:

Medicare	28%
Medicaid	1%
Commercial	66%
Self-Pay	2%
Workers Comp	1%
Uncomp Care	<u>2%</u>
Total	100%

There is no projected change with this project. *(July 16, 2005 CON Application, page 14 and March 16, 2005 completeness responses, page 18)*

46. The Applicant states that the payer mix only reflects 1% Medicaid because the hospitals have exclusive managed care contracts with Anthem Blue Cross, who in turn has a contract with the State of Connecticut to service this population and that in the past, the Applicant has requested participation in this provider panel, however, no participating provider status has been granted. *(August 29, 2005 Response to Interrogatories, Page 10)*
47. The Applicant provided free care to uninsured and underinsured patients in the primary service area in amounts that exceed three quarters of a million dollars. *(August 29, 2005 Response to Interrogatories, Page 10)*
48. The Applicant's financial projections "without the project" do not reflect a direct loss of \$900,000 as claimed by the Applicant. *(March 16, 2005 Completeness Responses, Page 18)*
49. There is no State Health Plan in existence at this time. *(July 16, 2004 CON Application, page 2)*
50. The Applicant's proposal is consistent with its long-range plan. *(July 16, 2004 CON Application, page 2)*
51. The Applicant does not have any teaching or research responsibilities. *(July 16, 2004 CON Application, page 9)*
52. There are no distinguishing characteristic of the Applicant's patient/physician mix that makes the proposal unique. *(July 16, 2004 CON Application, pages 9-10)*

53. The Applicant's rates are based on its projections which are estimated by the Applicant to cover the proposed capital expenditure and operating costs. (*July 16, 2004 CON Application, page 16*)
54. The Applicant has sufficient technical and managerial competence to provide efficient and adequate service to the public. (*July 16, 2004 CON Application, page 8*)
55. The Applicant has implemented various activities to improve productivity and contain costs including energy conservation, reengineering of its operations, the application of new technology and group purchasing. (*July 16, 2004 CON application, page 9*)

Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for proposed services on a case by case basis. Certificate of Need (“CON”) applications do not lend themselves to general applicability due to a variety and complexity 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 proposed services.

Robert D. Russo, M.D. & Associates, Radiology, P.C. (“Applicant” or “P.C.”) is a for-profit professional corporation which operates a multi-site private radiology practice in Fairfield County. The Applicant proposes to acquire a PET-CT scanner at the 2660 Main Street Bridgeport practice location and views this acquisition as an upgrade to its authorized CT scanning service.

The Applicant identifies the primary service area for the CON proposal as the towns of Ansonia, Bridgeport, Easton, Fairfield, Monroe, Norwalk, Seymour, Shelton, Stratford, Trumbull, Weston, Westport and Wilton. The Applicant identifies the secondary service area for the CON proposal as the towns of Darien, Milford, New Canaan, Ridgefield and Stamford. The Applicant performs 14,000 CT scans per year in its practice locations. The Applicant indicates that the proposed PET-CT scanner will be centrally located in Bridgeport. Patients in need of PET imaging who present at other practice locations will be sent to the Bridgeport location for imaging. PET or PET/CT services are currently available or authorized in the service area through the Fairfield County Mobile PET Collaborative, Advanced Radiology Consultants, HealthCenter Imaging, and Milford Hospital. The Fairfield County Mobile PET Collaborative includes Bridgeport Hospital, St. Vincent’s Medical Center, Norwalk Hospital and Danbury Hospital.

The Applicant based the need for the proposed PET/CT scanner on improvement in the quality of imaging services in the region; the provision of a full continuum of imaging services, loss of physician referrals and the aging of the population. With respect to the quality of imaging services in the region, the Applicant asserts that there is a lack of fellowship-trained Nuclear Medicine radiologists presently performing PET scans. The Applicant has stated that none of the Bridgeport hospitals in the Fairfield County Mobile PET Collaborative have a fellowship-trained nuclear radiologist. However, at Bridgeport Hospital, Dr. Charles I. Heller and Dr. Scott Charles Williams are both Board Certified in Nuclear Medicine and the American College of Radiology. Dr. Kevin Dickey of SVMC testified that by definition, all radiologists who are certified by the American Board of Radiology are qualified to interpret nuclear medicine as well as other imaging studies. The Applicant did not contest this. Further, the American College of Radiology does not require the presence of a fellowship-trained nuclear medicine radiologist in order to receive ACR accreditation. Therefore, OHCA concludes that contrary to the assertions of the Applicant, the existing providers of PET and PET/CT services at the Bridgeport hospitals employ qualified radiologists. The Applicant has not demonstrated the need based on the improvement in the quality of PET scanning services in the region.

The Applicant claims that its inability to perform PET scans has adversely affected its practice. According to the Applicant, referring physicians, in particular neurologists and oncologists, do not use the Applicant's existing imaging services because PET and PET/CT studies are not available. The Applicant claims that it is disruptive to the patient's care if the CT scan is done within the Applicant's office and the PET scan is done at another location, and neither the PET provider nor the Applicant have access to the images for comparison and fusion needs.

The Applicant claims that the practice's referring physicians often send their patients out of the area for PET scans. The referring physicians, who rely on the Applicant in consultation, expect the Applicant to be able to perform PET scanning and fusion imaging, where the images from PET, CT and MRI as well as Ultrasound can be merged into a single diagnostic result. The Applicant also asserts that referring physicians are not sending their patients to the existing PET providers serving Fairfield County and as a result, many of their patients are traveling out of state to access PET scanners. However, conflicting testimony was offered by SVMC and Bridgeport Hospital. Both Hospitals testified that they receive referrals from the oncologists, radiation oncologists and specialists that the Applicant claims are referring patients to out of state providers. SVMC provided documentation that demonstrates that every oncologist who signed the two letters of support for the Applicant's project have sent patients to SVMC for PET scanning in the past four months. In light of the above, OHCA concludes that the Applicant has not demonstrated in that referring physicians in this area are currently sending patients out of the region or the state for PET studies, for any specific reason, including the lack of qualified radiologists at existing providers.

The Applicant projects that it will perform 14,322 CT scans; 250, 375 and 500 PET scans for Years One, Two and Three, respectively; and 125 PET/CT scans during the first year of operation of the proposed equipment. According to the Applicant, this projection is based on historical requests for PET scans from referring physicians and the Applicant's analysis of recent CT volume. The Applicant analyzed a sampling of patient records and found that 450 CT studies were referred back to the referring physician with a recommendation for a PET study. The Applicant has not provided any supporting documentation regarding these data reports or the sampling of patient records. The Applicant has not indicated the size of the sample used. Then, based on a further analysis of diagnostic versus therapeutic intervention, the Applicant adjusted the number of PET scans due to the number of neoplasms and neurological conditions to reach the additional 250 procedures in the first year. Population growth and the increasing indications for use of PET for other conditions were also factored in as growth. In addition to the above, interviews with neurological and oncological colleagues as to their increasing use of PET scans were also factored into years two and three. No calculation of this methodology has been provided to OHCA.

The Applicant asserts that its needs assessment has shown that the Hospitals' mobile unit is not meeting the need for PET services within the service area where the need continues to grow along with the aging population. There has been no evidence provided to support this assertion. The Applicant states that the current scheduling backlogs in Fairfield County range from 5 to 7 days in the service area. Due to the mobile nature of the Collaborative's unit, there are only limited days available for PET scans at each Collaborative Hospital site. SVMC states that it is generally able to schedule patients for PET scanning within one week, that PET and PET-CT

scanning are diagnostic procedures that are non-emergent and scheduling patients within a week is clinically appropriate. The Applicant did not contest this testimony at the hearing. St. Vincent's Medical Center performed 368 PET scans in FY 2004. Since the mobile PET unit is available to both SVMC and BH 10 hours per day, one day per week, SVMC can handle capacity growth to 520 scans per year before needing to increase the amount of days contracted for with the scanner vendor. In addition, Bridgeport Hospital has the same capacity of 520 scans per year but had only provided 194 PET scans in FY 2004. Together SVMC and BH provided 562 scans in FY 2004. However, aggregating both hospitals' capacity, at one day each per week for 52 weeks, there is capacity for 1040 scans annually between these two existing PET providers. From this, OHCA concludes that there appears to be sufficient PET scanning capacity currently servicing the region and that with the already authorized upgrade of PET to PET/CT for the Fairfield County Mobile PET Collaborative hospitals, the PET-CT needs of the region will be addressed upon the initiation of the enhanced services.⁵ The Applicant did not identify the underserved patient population or quantify the unmet need that it believes currently exists for the proposed PET/CT unit. Therefore, OHCA finds that the Applicant has not demonstrated that the proposed PET/CT scanner would significantly improve either the quality or the accessibility of health care delivery in the region.

Finally, OHCA is concerned with the financial viability of this proposal. The total capital cost associated with the proposal is \$2,302,392, which includes a leasing of the PET scanner and renovations to physical space. The source of funding for renovations is operating funds. The Applicant is entering into a capital lease arrangement for the PET-CT unit. The Applicant estimates an incremental gain from operations for the first three years of the project, specifically, \$1,198, \$55,516 and \$269,735, for year one, year two and year three, respectively. The financial viability rests on the ability of the Applicant to achieve its utilization projections. Since the Applicant's volume projections are questionable because they were unsubstantiated, the financial projections upon which they are based are also questionable and unsubstantiated. Therefore, OHCA finds that the Applicant has not demonstrated that the CON proposal is either financially feasible or cost effective.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Robert D. Russo, M.D. & Associates Radiology, P.C. to acquire a fixed positron emission tomography / computed tomography scanner for its 2660 Main Street Bridgeport practice location, at a total capital cost of \$2,302,392, is hereby DENIED.

⁵ The Collaborative hospitals have not yet implemented this upgrade to PET/CT and the CON for that upgrade currently has a CON expiration date of August 6, 2005 by which time the Collaborative hospitals must fully implement the authorized project or the CON will lapse and no longer be valid.

Order

The proposal of Robert D. Russo, M.D. & Associates Radiology, P.C. proposes to acquire a fixed positron emission tomography/computed tomography scanner for its 2660 Main Street Bridgeport practice location at a total capital cost of \$2,302,392, is hereby denied.

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

June 10, 2005

Signed by Cristine A. Vogel
Commissioner

CAV:kr