



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Naugatuck Valley Radiological Associates,
P.C./Southbury Holding, LLC and Northeast
Radiology, P.C./Radcorp of Southbury, LLC
d/b/a PET-CT of Southbury, LLC

Docket Number: 06-30875-CON

Project Title: Lease and Operation of a Mobile PET-CT Scanner
One Day Per Week in Southbury, CT

Statutory Reference: Sections 19a-638 & 19a-639, C.G.S.

Filing Date: May 31, 2007

Hearing Date: July 18, 2007

Intervenors: The Waterbury Hospital
The Harold Leever Regional Cancer Center
Danbury Hospital

Hearing Officer: Cristine A. Vogel, Commissioner

Decision Date: August 15, 2007

Default Date: August 29, 2007

Staff Assigned: Alexis G. Fedorjaczenko
Steven W. Lazarus

Project Description: Naugatuck Valley Radiological Associates, P.C./Southbury Holding, LLC and Northeast Radiology, P.C./Radcorp of Southbury, LLC d/b/a PET-CT of Southbury, LLC (“Applicant” or “PCS”) proposes to lease and operate a mobile PET-

CT scanner one day per week in Southbury, CT, at an associated capital expenditure of \$2,450,000.

Nature of Proceedings: On May 31, 2007, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from the Applicant for the lease and operation of a mobile PET-CT scanner one day per week in Southbury, CT, at an associated capital expenditure of \$2,450,000. PET-CT of Southbury, LLC is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

A notice to the public concerning OHCA’s receipt of the Applicant’s Letter of Intent was published on December 24, 2006 in the *Republican American* (Waterbury) and on December 29, 2006 *The News Times* (Danbury). Pursuant to Sections 19a-638 and 19a-639 C.G.S. three individuals or an individual representing an entity with five or more people had until June 21, 2007, the twenty-first calendar day following the filing of the Applicant’s CON Application, to request that OHCA hold a public hearing on the Applicant’s proposal. On June 13, 2007, OHCA received requests from Danbury Hospital and the Harold Leever Regional Cancer Center to hold a public hearing in this matter.

Pursuant to Sections 19a-638 & 19a-639, C.G.S., a public hearing regarding the CON application was held on July 18, 2007. On June 15, 2007, the Applicant was notified of the date, time and place of the hearing. On June 17, 2007, a notice to the public was published in the *Republican American*. On June 18, 2007, a notice to the public was published in *The News Times* (Danbury). Commissioner Cristine A. Vogel served as Presiding Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 & 19a-639, C.G.S.

By petition dated July 13, 2007, The Waterbury Hospital requested Party or, in the alternative, Intervenor status regarding the Applicant’s CON application. On July 13, 2007, the Presiding Officer designated The Waterbury Hospital as an Intervenor with full rights of cross-examination.

By petition dated July 13, 2007, The Harold Leever Regional Cancer Center requested Party or, in the alternative, Intervenor status regarding the Applicant’s CON application. On July 13, 2007, the Presiding Officer designated The Harold Leever Regional Cancer Center as an Intervenor with full rights of cross-examination.

By petition dated July 13, 2007, Danbury Hospital requested Intervenor status regarding the Applicant’s CON application. On July 13, 2007, the Presiding Officer designated Danbury Hospital as an Intervenor with full rights of cross-examination.

OHCA’s authority to review and approve, modify or deny the CON application is established by Sections 19a-638 & 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. PET-CT of Southbury, LLC ("Applicant" or "PCS"), located at 385 Main Street South, Southbury, is a limited liability company whose members include Southbury Holding, LLC and Radcorp of Southbury, LLC. *(March 15, 2007, Initial CON Application, pages 4-5 and November 27, 2006, Letter of Intent)*
2. Southbury Holding, LLC and Radcorp of Southbury, LLC are subsidiaries of Naugatuck Valley Radiology Associates, P.C. ("NVRA") and Northeast Radiology, P.C., ("NER") respectively. NVRA and NER are professional corporations comprised of radiologists who offer comprehensive full service imaging services. *(March 15, 2007, Initial CON Application, pages 4-5 and November 27, 2006, Letter of Intent)*
3. The Applicant, PCS, is a newly established entity and does not currently offer any services. *(March 15, 2007, Initial CON Application, page 7)*
4. At the proposed PCS location, Radcorp of Southbury, LLC and Southbury Holding, LLC, as members of Diagnostic Imaging of Southbury ("DIS"), currently provide comprehensive imaging services including the modalities of diagnostic radiography, fluoroscopic radiology, CT, ultrasound, mammography, bone densitometry, nuclear medicine, and high field MRI. *(May 31, 2007, Completeness Response, page 2)*
5. PCS is requesting authorization to lease and operate a mobile PET-CT scanner one day per week. The proposed scanner would be a Philips Gemini Open PET-CT scanner leased from Mobile PET-CT Associates, LLC ("Integral Mobile"). *(March 15, 2007, Initial CON Application, page 7)*
6. PCS' primary service area ("PSA") includes the towns of Southbury, Woodbury, and Newtown. *(March 15, 2007, Initial CON Application, page 13)*
7. PCS' secondary service area ("SSA") includes the towns of Waterbury, Watertown, Oxford, Naugatuck, Middlebury, and Bethlehem. *(March 15, 2007, Initial CON Application, page 13)*
8. According to PCS, the PSA and SSA towns were selected based on the PSA and SSA towns for DIS, because it is anticipated that PCS and DIS will share radiologists, physician referral patterns, and an office location. *(March 15, 2007, Initial CON Application, page 14 and May 31, 2007, Completeness Response, page 2)*

9. The Applicant claimed that the need for the proposed PET-CT scanner is based on the following: (*March 15, 2007, Initial CON Application, pages 15-22*)

- There are no PET-CT providers in the PSA and the only PET-CT provider in the SSA is a cancer center;
- Community-based referring physicians support the proposal;
- PCS' physicians have the training, knowledge, and experience to provide high-quality PET-CT services;
- This project would utilize a digital network to enhance referring physicians' access to their patients' image data;
- Increase in the size of the aging population; and
- Expected continued demand for cardiac and neurology PET-CT services due to advances in technology and clinical applications.

10. The Applicant testified that by offering new services and new technologies, the proposal is intended to: (*July 18, 2007, Public Hearing, Applicant Testimony and August 3, 2007, Applicant's Response to the Intervenor's Late-File Responses*)

- Ensure that the existing imaging center stays state-of-the-art;
- Prevent the existing imaging center from becoming outdated; and
- Allow the existing imaging center to retain their patient base.

11. The Applicant proposes to focus on neurology and cardiac PET-CT scans and is projecting the following PET-CT scan volume for FYs 2007-2010: (*May 31, 2007, Completeness Response, page 6; March 15, 2007, Initial CON Application, page 23 and July 25, 2007, Late File No. 1*)

Table 1: PCS Projected PET-CT Scans for FYs 2007-2010

Scan Type	2007*	2008	2009	2010
Neurology	8	36	47	71
Cardiac	60	192	217	217
Total	68	228	264	288

* 2007 volume projections are for four months.

Note: The proposed mobile PET-CT scanner would be at the proposed site one day per week (Mondays) with a commitment to the vendor to provide a minimum of four scans per day.

12. The projected PET-CT scans are based on the following: PCS radiologist experience providing PET reading volume at The Harold Leever Regional Cancer Center of 355, 382, and 510 in FY's 2004, 2005, and 2006, respectively, at New Milford Hospital of 102, 178, and 257 in FY's 2004, 2005, and 2006, respectively, and for Connecticut patients in New York state of 39 and 95 in FY's 2005 and 2006, respectively; historical dementia/neurology scans volume on NER's mobile PET-CT in Brewster, NY; discussions with referring physicians and their office staff; estimates provided by referring physicians of potential monthly PET-CT cardiac scan volumes; and industry publications projecting future demand for PET-CT scans. (*May 31, 2007, Completeness Response, page 6; March 15, 2007, Initial CON Application, pages 23-4 & 30*)

13. The following PET-CT or PET providers are currently serving the residents of the Applicant's PSA:

Table 2: PET-CT Providers Serving the Proposed Primary Service Area ("PSA")

Provider	Type	Scan Types	Service Area ³
The Harold Leever Regional Cancer Center ¹	Fixed	Oncology, Cardiac, Neurological	Beacon Falls, Bethlehem, Cheshire, Middlebury, Morris, Naugatuck, Oakville, Oxford, Plantsville, Plymouth, Prospect, <u>Southbury</u> , Thomaston, Waterbury, Watertown, Wolcott, <u>Woodbury</u> ,
Danbury Hospital ²	Mobile, upgrading to Fixed in 9/07	Oncology, Cardiac, Neurological	Bethel, Bridgewater, Brookfield, Danbury, Kent, Monroe, New Fairfield, New Milford, <u>Newtown</u> , Redding, Ridgefield, Roxbury, Sherman, <u>Southbury</u> , Washington, Wilton, <u>Woodbury</u>

1. The Harold Leever Regional Cancer Center in Waterbury is a joint venture partnership of Saint Mary's Hospital and Waterbury Hospital. 03-30200-CON, Replacement of an Existing CT Scanner and Mobile PET Scanner with a Fixed PET-CT Scanner, November 14, 2004

2. Danbury Hospital's fixed PET-CT scanner was approved under Docket Number 04-30903-CON, Construct and Operate Outpatient Diagnostic Building, Construct Parking Garage and Expand Outpatient Dialysis Services, February 10, 2006

3. PCS' proposed PSA towns are underlined.

14. The Harold Leever Regional Cancer Center is not currently operating at capacity. (July 18, 2007, Public Hearing, Intervenor Testimony)
15. Danbury Hospital is not currently operating at capacity. (July 18, 2007, Public Hearing, Intervenor Testimony)
16. Danbury Hospital currently offers free transportation from the center of Southbury to the Danbury Hospital campus with departures of two to three times a day. (July 18, 2007, Public Hearing, Intervenor Testimony)
17. The Applicant did not provide the following:
- Needs assessment;
 - Referring physicians at the Public Hearing to testify in support of the application;
 - Evidence of where residents of the service area are currently receiving PET-CT services;
 - Demonstrated backlog of patients unable to access PET-CT services in the service area; and
 - Data to support the projected neurology-related scan growth.
18. Nationally and in the proposed service area, about 85% of total PET-CT scan volume is comprised of oncology PET-CT scans and about 15% is comprised of non-oncology (neurology and cardiac) PET-CT scans. (July 18, 2007, Public Hearing, Applicant and Intervenor Testimony)
19. The Applicant did not project any oncology PET-CT scan volume, but indicated that the proposed PET-CT scanner will have the capability of performing oncology-related scans and that if a patient requests or is referred to PCS for an oncology-

related scan, PCS will perform the scan. (*May 31, 2007, Completeness Response, page 7 and July 18, 2007, Public Hearing, Applicant Testimony*)

20. The Applicant did not provide sufficient evidence on the following: (*July 18, 2007, Public Hearing*)
- Names and qualifications of the cardiologists who will be present and provide services during cardiac PET-CT scans; and
 - Research supporting new treatment methods used with early-diagnosed dementia.
21. The Applicant testified that referring physicians have final authority regarding what type of study is requested and where that study is done. (*July 18, 2007, Public Hearing, Intervenor Testimony*)

Financial Feasibility and Cost Effectiveness of the Proposal and its Impact on the Applicant'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

22. The proposed total capital expenditure associated with this proposal is as follows: (*March 15, 2007, Initial CON Application, page 43*)

Table 3: Proposed Total Capital Expenditure

Non-Medical Equipment (Purchase)	\$28,000
Construction/Renovation	\$22,000
Total Capital Expenditure	\$50,000
Major Medical Equipment (Lease, FMV)	\$2,400,000
Total Capital Cost	\$2,450,000

23. The Applicant's current and three year projected payer mix for the proposed mobile PET-CT service based on Net Patient Revenue are as follows: (*March 15, 2007, Initial CON Application, page 49*)

Table 4: Current & Three-Year Projected Payer Mix

Description	Current	Year 1	Year 2	Year 3
Medicare	-	36.2%	36.2%	36.2%
Medicaid	-	1.0%	1.0%	1.0%
Total Government	-	37.2%	37.2%	37.2%
Commercial Insurers	-	61.2%	61.2%	61.2%
Uninsured	-	0.6%	0.6%	0.6%
Workers Compensation	-	1.0%	1.0%	1.0%
Total Non-Government	-	62.8%	62.8%	62.8%
Total Payer Mix	-	100%	100%	100%

24. PCS reported projected net income/(losses) incremental to the project of (\$5,427), \$35,373, \$57,619, and \$63,690 for FYs 2007, 2008, 2009, and 2010, respectively. (*July 25, 2007, Late File No. 2*)

25. There is no State Health Plan in existence at this time. *(March 15, 2007, Initial CON Application, page 8)*
26. The proposal is consistent with the Applicant's long-range plan. *(March 15, 2007, Initial CON Application, page 9)*
27. The Applicant's proposal will not change the Applicant's teaching or research responsibilities. *(March 15, 2007, Initial CON Application, page 40)*
28. There are no distinguishing characteristics of the patient/physician mix with regard to the proposal. *(March 15, 2007, Initial CON Application, page 40)*
29. Southbury Holding, LLC and Radcorp of Southbury, LLC, d/b/a Diagnostic Imaging of Southbury, have improved productivity and contained costs through application of new technologies and reengineering of operations. *(May 31, 2007, Completeness Response, page 9)*
30. The Applicant has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(March 15, 2007, Initial CON Application, pages 98-127)*

Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for the proposed service on a case by case basis. Certificate of Need (“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 proposed services.

PET-CT of Southbury, LLC (“Applicant” or “PCS”), located at 385 Main Street, Southbury, is a limited liability company whose members include Southbury Holding, LLC and Radcorp of Southbury, LLC. The Applicant is requesting authorization to lease and operate a mobile PET-CT scanner one day per week. PCS is a newly established entity that does not currently offer any services. However, comprehensive imaging services are currently offered at the proposed PCS location through Diagnostic Imaging of Southbury, LLC, whose members also include Radcorp of Southbury, LLC and Southbury Holding, LLC. The Applicant testified that by offering new services and new technologies, the proposal is intended to ensure that this existing imaging center stays state-of-the-art and that its physicians retain their patient base. Given the lack of demonstrated need for additional PET-CT scanning services in the proposed service area, this appears to be the Applicant’s basis for proposing to provide mobile PET-CT services in Southbury.

The Applicant asserted that the proposed mobile PET-CT service in Southbury is needed because there are no PET-CT providers in the proposed primary service area (“PSA”) and the only PET-CT provider in the secondary service area is a cancer center. However, OHCA finds that residents of the proposed service area have appropriate access to PET-CT scanners. There is a mobile PET-CT scanner that can perform oncology, cardiac, and neurological scans at Danbury Hospital, with an OHCA approved fixed scanner scheduled to be operational in September, 2007. Access to this scanner is facilitated by free transportation offered by Danbury Hospital from the center of Southbury to the Hospital campus. There are also no limitations that prevent The Harold Leever Regional Cancer from doing cardiac and neurological PET-CT scans in addition to oncology scans. Both Danbury Hospital and The Harold Leever Regional Cancer Center testified at the Public Hearing that they are not at capacity. The availability and capacity of other PET-CT providers that serve the Applicant’s proposed PSA lead OHCA to question the need for the proposed mobile PET-CT scanner.

The Applicant claimed that the proposed service is needed because of continued demand for neurology and cardiac PET-CT services due to advances in technology and clinical applications. The Applicant also asserted that community-based referring physicians support the proposal. However, the Applicant’s volume projections are flawed based on a lack of demonstrated evidence. There were no referring physicians present at the Public Hearing to testify in support of the application. No evidence was presented to demonstrate where residents of the PSA are currently being referred for cardiac and neurology PET-CT

scans or that there is a backlog of patients unable to access these PET-CT services in the service area. Furthermore, although oncology PET-CT scans comprise about 85% of total PET-CT scans, both nationally and in the service area, the Applicant did not project any oncology-related PET-CT scan volume. Rather, the Applicant proposes to focus on neurology and cardiac scans that comprise only about 15% of total PET-CT scan volume. Given the lack of data to support the projected neurology and cardiac scan volume, it is unclear whether the exclusion of projected oncology scans is realistic.

The capital cost associated with the proposal is \$2,450,000. The Applicant projected net income/(losses) incremental to the project of (\$5,427), \$35,373, \$57,619, and \$63,690 for FYs 2007, 2008, 2009, and 2010. Since OHCA cannot conclude that the projected volumes accurately reflect the need for PET-CT services in the area, OHCA finds that the financial projections, which are based on the projected volumes, are questionable. Therefore, OHCA does not find the Applicant's proposal to be financially feasible or cost-effective. In summary, OHCA cannot conclude definitively that there is a need for the proposed mobile PET-CT scanner at this time.

Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Naugatuck Valley Radiological Associates, P.C./Southbury Holding, LLC and Northeast Radiology, P.C./Radcorp of Southbury, LLC d/b/a PET-CT of Southbury, LLC's to lease and operate a mobile PET-CT scanner one day per week in Southbury, CT at a total capital expenditure of \$2,450,000, is hereby **DENIED**.

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

August 15, 2007

Signed by Cristine A. Vogel
Commissioner

CAV; agf; swl