



Office Of Health Care Access Certificate of Need Application

Final Decision

Applicant: Northwestern Connecticut Oncology/Hematology Associates, LLP

Docket Number: 05-30510-CON

Project Title: Proposal to Acquire and Operate Fixed Positron Emission Tomography Scanner

Statutory Reference: Section 19a-638 of the Connecticut General Statutes

Filing Date: March 7, 2006

Hearing Date: April 26, 2006

Intervenor: Radiological Society of Connecticut

Presiding Officer: Cristine A. Vogel

Decision Date: May 22, 2006

Default Date: June 5, 2006

Staff Assigned: Laurie K. Greci

Project Description: Northwestern Connecticut Oncology/Hematology Associates, LLP (“Applicant”) proposes to acquire and operate a Positron Emission Tomography Scanner (“PET”), at a total capital cost of \$235,300.

Nature of Proceedings: On March 7, 2006, the Office of Health Care Access (“OHCA”) received the Certificate of Need (“CON”) application from Northwestern Connecticut Oncology/Hematology Associates, LLP (“Applicant”) seeking authorization to acquire and operate a Positron Emission Tomography Scanner (“PET”), at a total capital cost of \$235,300. The Applicant is a health care facility or institution as defined in Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

A notice to the public concerning OHCA's receipt of the Applicants' Letter of Intent to file its CON application was published in *The Register Citizen* (Torrington) on October 7, 2005, pursuant to Section 19a-638, C.G.S. OHCA received no responses from the public concerning the Applicants' Letter of Intent.

Pursuant to Section 19a-638, C.G.S., a public hearing regarding the CON application was held on April 26, 2006. On March 30, 2006, the Applicant was notified of the date, time and place of the hearing. A notice to the public was published in *The Register Citizen* (Torrington), on April 4, 2006. 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 Section 19a-638, C.G.S.

By petition dated April 20, 2006, Radiological Society of Connecticut, Inc. requested Intervenor status regarding the CON application. The Presiding Officer designated Radiological Society of Connecticut, Inc. as an Intervenor with limited rights of participation.

OHCA's authority to review and approve, modify or deny the CON application is established by Section 19a-638, 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. Northwestern Connecticut Oncology/Hematology Associates, LLP ("NWCOHA" or "Applicant") is an office-based physicians practice located at 200 Kennedy Drive, Torrington, Connecticut with additional offices in Sharon and New Milford. (*December 23, 2005, Initial CON Submission, page 2*)
2. NWCOHA proposes to lease a fixed positron emission tomography ("PET") scanner from US Oncology ("USON") and provide PET scanning services to its patients. (*December 23, 2005, Initial CON Submission, page 2*)
3. Under OHCA Docket Number 06-30510-DTR, it was determined that NWCOHA is a central services facility as it will be contracting with a separate legal entity to read and interpret the scans and that USON is the owner of the equipment and has a management agreement with NWCOHA and will be able to advise NWCOHA. (*September 29, 2005, CON Determination Report for Docket Number 06-30510-DTR*)
4. The Center for Cancer Care ("The Center"), located at 200-220 Kennedy Drive in Torrington, was founded in 1997 as a collaborative effort of NWCOHA and The

Charlotte Hungerford Hospital (“CHH”). The Applicant stated that the central mission of The Center is to provide the most current, highest quality, cancer care to the residents of northwest Connecticut in an outpatient setting. The Center offers medical oncology, radiation oncology, laboratory and infusion services, and complimentary therapies. *(December 23, 2005, Initial CON Submission, page 2)*

5. NWCOHA provides the medical oncology and hematology services at The Center. Services provided include patient examination, laboratory testing, and medical therapies, such as chemotherapy and other ancillary medication, administered by infusion or injection. NWCOHA also offers their cancer patients access to breakthrough therapies and new agents through the practice’s participation in clinical trials. *(December 23, 2005, Initial CON Submission, page 2)*
6. CHH provides the radiation oncology services offered at The Center. *(December 23, 2005, Initial CON Submission, page 3)*
7. The Hungerford Diagnostic Center (“Diagnostic Center”), operated by Advanced Medical Imaging, is located at 220 Kennedy Drive. It is a joint venture of CCH and Torrington Radiologists, P.C. The Diagnostic Center offers computed tomography (“CT”), ultrasound, magnetic resonance imaging, plain film x-rays, and bone densitometry. *(December 23, 2005, Initial CON Submission, page 3)*
8. US Oncology is a company that manages oncology physician practices throughout the United States and is the business manager for NWCOHA. *(December 23, 2005, Initial CON Submission, page 280)*
9. NWCOHA proposes to utilize the PET scanner for the detection, staging, and management of disease of cancer patients under the practice’s care. The detection of metastatic disease can affect the management and treatment options of cancer patients. *(December 23, 2005, Initial CON Submission, page 11)*
10. The Applicant’s service area is provided in the following table:

Table 1: Service Area of NWCOHA

Service Area	Towns
Primary	Connecticut towns of Barkhamsted, Bethlehem, Bridgewater, Canaan, Colebrook, Cornwall, Goshen, Harwinton, Kent, Litchfield, Morris, New Hartford, New Milford, Norwalk, Plymouth, Roxbury, Salisbury, Sharon, Thomaston, Torrington, Warren, Watertown, Washington, Winchester, and Woodbury
Secondary	Massachusetts towns of Great Barrington and Sheffield. New York towns of Millerton, Amenia, Marlborough, Brewster, Pawling, and Patterson

(December 23, 2005, Initial CON Submission, page 4)

11. The current providers of PET scanning within the Applicant's primary service area are CHH and New Milford Hospital. The two hospitals offer PET scanning service once a week with a mobile PET scanner through a contract with Alliance Imaging. In FY 2005, CHH completed 276 PET scans and New Milford Hospital completed 150 scans. *(March 7, 2006, CON Completeness Response, page 11 and Schedule 500 for FY 2005, Charlotte Hungerford Hospital and New Milford Hospital)*

12. The Applicant based the need to acquire the fixed PET scanning services on the following factors:
 - To assist in the diagnosis and management of the cancer patients under treatment by NWCOHA;
 - Provide a more accessible PET service as CHH's service is available only one day per week;
 - PET is currently underutilized and demand will increase as physicians and patients become more familiar with its use; and
 - With the addition of PET, cancer patients will have access to the full complement of outpatient diagnostic and treatment modalities in a single outpatient setting. *(December 23, 2005, Initial CON Submission, pages 6 to 8)*

13. In January 2005 the CMS¹ issued a Decision Memo that determined there was sufficient evidence to conclude that a PET scan is reasonable and necessary as an adjunct test under certain provisions for the detection of cancer. The National Oncologic PET Registry ("Registry") was developed in response to the CMS proposal. The Registry will expand coverage for PET to include cancers and indications not presently eligible for Medicare reimbursement. NWCOHA states that it will participate in the Registry. The Applicant must provide data to the Registry that includes the scan performed and the impact of the PET scan on the cancer patient's management by the practice. *(December 23, 2005, Initial CON Submission, pages 7 and 8 and Exhibit 4-A.i(d)3)*

14. According to the Applicant, in the twelve months prior to the date of the initial CON application submission, NWCOHA reported seeing 565² new patients that had cancer types and tumor sites appropriate for PET imaging. Using USON actual data from oncology physician throughout the United States, NWCOHA determined that 50% of eligible cancer patients who might have benefited from PET scanning would actually need a PET scan on the basis of clinical utility. Of those patients that received a first PET scan, half of these patients would receive a second scan for an average of 1.5 PET scans per patient. Therefore 424³ PET scans for NWCOHA patients would have been ordered during the reported time period. *(December 23, 2005, Initial CON Submission, page 10)*

¹ CMS is the Centers for Medicare & Medicaid Services. Formerly known as the Health Care Financing Administration (HCFA), we are the federal agency responsible for administering the Medicare, Medicaid, SCHIP (State Children's Health Insurance), HIPAA (Health Insurance Portability and Accountability Act), CLIA (Clinical Laboratory Improvement Amendments), and several other health-related programs.

² NOTE: The data reported by the Applicant could not be verified by OHCA.

³ 565 patients X 50% eligibility rate X 1.5scans per patient = 424 scans.

15. The Applicant used a 1.67% growth rate for each year for the cancer incidence in the service area, the Applicant's projected PET scan volume for Fiscal Years 2006, 2007, and 2008 are 431, 438, and 445 scans⁴, respectively. (*December 23, 2005, Initial CON Submission, page 10*)
16. NWCOHA also reported that in 2004 there were 943 people from their primary service area who had been diagnosed with cancers that would have made them eligible to receive PET imaging services, including those cancer types covered under the PET Registry authorized by CMS. Using the same methodology to determine the number of PET scans in the primary service area, NWCOHA determined the following:

Table 2: PET Eligible Cancer Patients in Primary Service Area

Fiscal Year	Number of PET Scans		
	2006	2007	2008
Application of 1.67% growth rate per year to the initial 943 people	975	991	1,008
50% eligibility rate	487	496	504
1.5 scans per patient	731	743	756
Number of scans projected for NWCOHA patients (as reported in Finding of Fact 14)	431	438	445
Scans to be performed by CHH	300	305	310

NOTE: OHCA cannot verify the Applicant's projections.
(*December 23, 2005, Initial CON Submission, pages 5, 6, and 9*)

17. Matthew E. Brow, the National Director of Government Relations and Public Policy for US Oncology, testified that:
- US Oncology will augment the scanner's software to allow the fusion of a patient's PET scan with a CT scan performed at the Diagnostic Center;
 - Being a relatively new technology, PET scanning service is being underutilized; and
 - Applications of PET are increasingly being covered by CMS and demand will be increasing.
- (*April 26, 2006, Prefiled Testimony and Hearing Testimony of Matthew Brow*)

⁴ OHCA cannot verify these projections.

**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**

18. The total proposed capital cost for the proposal is presented in the following table:

Table 3: Proposed Capital Cost

Item	Cost
Medical Equipment, purchase	\$45,000
Non-medical Equipment, purchase	10,000
Total Capital Expenditure	\$55,000
Medical Equipment, fair market value of leased PET scanner	150,000
Taxes, Delivery and Installation Charges	30,300
Total Capital Cost	\$235,300

(December 23, 2005, Initial CON Submission, page 19).

19. NWCOHA will lease a Siemens ECAT EXACT PET scanner from USON. *(December 23, 2005, Initial CON Submission, pages 6 and 280).*
20. NWCOHA will bill for the PET scanning service. *(December 23, 2005, Initial CON Submission, page 18)*
21. NWCOHA will employ an American Registry of Radiologic Technologists certified nuclear medicine technologist to perform the PET scans and handle the radiopharmaceuticals. *(March 7, 2006, CON Completeness Response, page 13)*
22. NWCOHA will contract with Torrington Radiologists, P.C. to read and interpret the PET scans; it has been providing PET interpretation and supervision for CHH's PET program since 2002. Torrington Radiologists, P.C. has adopted and follows the American College of Radiology Guidelines for the services that its physicians provide. *(December 23, 2005, Initial CON Submission, page 14)*
23. NWCOHA proposes to operate the PET scanner three days per week. The initial hours of operations will be on Mondays, Wednesdays, and Thursdays from 8:00 a.m. to 5:00 p.m. *(December 23, 2005, Initial CON Submission, page 12)*

24. The Applicant is projecting incremental increases in operating revenue relating to the proposal for the first three years of operations as follows:

Table 4: Projected Incremental Increases Due to Applicant's Proposal

	FY 2006	FY 2007	FY 2008
<i>Number of Scans</i>	431	438	445
<i>Technical Fee</i>	\$2,300	\$2,150	\$2,050
Total Incremental Net Revenue*	\$991,300	\$941,700	\$912,250
FDG and Medical Supplies*	135,765	137,970	140,175
Fixed Costs**	416,402	500,819	500,897
Total Incremental Expenses	552,167	638,788	641,142
Net Incremental Operating Revenue	\$439,133	\$302,912	\$271,108

*FDG Costs \$275 per scan and Medical Supplies cost \$40 per scan.

**Includes salaries, benefits, rent, service agreement, taxes, general, administrative, and marketing costs, cost of capital and depreciation.

(December 23, 2005, Initial CON Submission, page 282)

25. The Applicant stated that most modern cancer treatment modalities, primarily chemotherapy, radiation therapy, and surgery, are difficult for the patient and expensive for the payer. The use of PET imaging is beneficial to the patient and payer in the following ways:

- PET imaging often obviates the need for invasive diagnostic procedures;
- Accurate staging of disease with PET improves a physician's ability to prescribe the appropriate treatment protocol for the patient;
- The use of PET imaging in monitoring tumor response to treatment allows physicians to discontinue ineffective treatments;
- The use of PET imaging for re-staging following completion of a course of therapy allows the physician to determine whether the treatment was complete successful or whether residual disease remains and patients can often avoid unneeded treatments;
- The use of PET imaging to plan radiation therapy treatments results in more accurate shaping of the radiation beams and more accurate modulation of radiation intensity helping to preserve health tissue and reducing side effects for patients; and
- All of these benefits help patients avoid the inconvenience and trauma of invasive procedures and hospitalization by allowing patients to treat and manage their disease in a more convenient, and often less costly outpatient setting.

(December 23, 2005, Initial CON Submission, Appendix VI)

26. There is no State Health Plan in existence at this time. *(December 23, 2005, Initial CON Submission, page 3)*

27. The Applicant has adduced evidence that the proposal is consistent with its long-range plan. *(December 23, 2005, Initial CON Submission, page 3)*

28. The Applicant did not report how it improved productivity or contained costs for the past year. *(March 7, 2006, CON Completeness Response, page 12)*

29. The proposal will not result in any changes to the Applicant's teaching and research responsibilities. *(December 23, 2005, Initial CON Submission, page 16)*
30. The Applicant reported that the cancer incidence rates in Litchfield County are greater than the cancer incidence rates in the State of Connecticut as a whole making its patient/physician mix unique. The Litchfield County average cancer incidence is approximately 7.4% higher than the stage average in 2005 and 7.9% higher than the stage average in 2010. *(December 23, 2005, Initial CON Submission, page 17)*
31. The Applicant has sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. *(December 23, 2005, Initial CON Submission, pages 223 to 256)*
32. The Applicant's rates are sufficient to cover the proposed capital cost and operating costs associated with the proposal. *(December 23, 2005, Initial CON Submission, pages 274 and 282)*

Rationale

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

Northwestern Connecticut Oncology/Hematology Associates, LLP (“NWCOHA”) proposes to acquire a fixed position emission tomography (“PET”) scanner for its office-based medical oncology/hematology practice in Torrington. US Oncology, a company that manages oncology physician practices throughout the United States and is the business manager for NWCOHA, is the owner of the PET scanner to be leased to NWCOHA. NWCOHA will contract with Torrington Radiologists, P.C. to read and interpret the PET scans.

NWCOHA stated that the central mission of The Center is to provide the most current, highest quality, cancer care to the residents of northwest Connecticut in an outpatient setting. As part of that central mission, NWCOHA proposes to add a PET scanner to expand the outpatient diagnostic and treatment modalities available at The Center to make it a complete, single outpatient setting for the care of cancer patients. NWCOHA also based its proposal on the enhancement to the practice’s ability to diagnose and manage their patients’ cancers that the PET scanning service will provide. The addition of the PET scanning service to The Center will give to patients a valuable imaging modality in a more accessible environment and location. OHCA finds that the CON proposal will improve both the quality and accessibility of PET scanning services and enhance the continuity of care to patients of northwest Connecticut.

In the twelve months prior to the date of its initial CON application submission, NWCOHA reported seeing 565 new patients that had cancer types and tumor sites appropriate for PET imaging. Applying an eligibility rate of 50%, and a scan frequency rate of 1.5 scans per patient, NWCOHA determined that 424 PET scans would have been ordered on their patients during that twelve month period. Although OHCA cannot verify the current rates of cancer incidence, it appears that NWCOHA has the patient base to support the fixed PET service at its practice.

The total capital expenditure for the CON proposal is \$235,300 which includes the PET scanner and associated equipment and software, and the renovations required to the physicians’ office. NWCOHA projects incremental gains in operating revenue related to the proposal of \$439,133, \$302,912, and \$271,108 for Fiscal Years 2006, 2007, and 2008. Although OHCA cannot draw any conclusions, NWCOHA’s projected PET scan volumes and the anticipated financial gains appear to be reasonable and achievable. Therefore, OHCA finds that the CON proposal is both financially feasible and cost effective.

Based on the foregoing Findings of Fact and Rationale, the Certificate of Need request of Northwestern Connecticut Oncology/Hematology Associates, LLP to acquire and operate a PET scanner, at a total capital expenditure of \$235,300, is hereby GRANTED.

Order

Northwestern Connecticut Oncology/Hematology Associates, LLP (“Applicant”) is hereby authorized to acquire a Positron Emission Tomography Scanner (“PET”) and establishing PET scanning service to be located at 200 Kennedy Drive, Torrington, at a total capital expenditure of \$235,300, subject to the following conditions:

1. This authorization shall expire on May 22, 2007. Should operation of the PET scanning service not be completed by that date, the Applicant must seek further approval from OHCA to complete the project beyond that date.
2. The Applicant shall not exceed the approved total capital expenditure of \$235,300. In the event that the Applicant learns of potential capital expenditure increases or expects that final project expenditures will exceed those approved, the Applicant shall file with OHCA a request for approval of the revised CON project budget.
3. The Applicant may only provide the PET scanning service to its own patients. Patients from other providers may not be referred to Northwestern Connecticut Oncology/Hematology Associates, LLP for the specific and sole purpose of receiving a PET scan. If the Applicant intends to change the population served, a CON determination shall be filed with OHCA.
4. Only physicians who are partners of Northwestern Connecticut Oncology/Hematology Associates, LLP may utilize the PET scanning service for their patients. The Applicant may not contract with other physician practices or specialty groups to perform PET scanning services.
5. Any change in ownership, termination of the PET scanning service, or relocation of the PET scanning service will require prior authorization from the Office of Health Care Access.
6. Any physician engaged by the Applicant to provide professional radiological services in relation to the PET scanning service must have obtained a license from the State of Connecticut to provide such services.
7. The Applicant shall file with OHCA utilization statistics for the fixed PET scanning service on a quarterly basis for two full years of operation. 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 scanning service commenced operation. The quarterly reports shall be filed by the Applicant and include the following information:
 - Total number of scans scheduled for the fixed PET scanner;
 - Total number of scans performed by the fixed PET scanner;
 - Average patient waiting time from the scheduling of the scan to the performance of the scan;

- Number of scans by patient zip code;
- Hours and days of operation for each week and in total; and
- Number of scans by Medicare diagnostic code.

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

May 22, 2006

Signed by Cristine A. Vogel
Commissioner

CAV: lkg