



## Office of Health Care Access Certificate of Need Application

### Final Decision

**Applicants:** Alliance Imaging, Inc.  
Lawrence & Memorial Hospital

**Docket Number:** 01-565

**Project Title:** Establish a Mobile Positron Emission Tomography  
("PET") Scanning Service

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

**Filing Date:** June 4, 2002

**Hearing:** Waived

**Decision Date:** June 21, 2002

**Default Date:** September 2, 2002

**Staff:** Laurie Greci  
Sandra Czunas

**Project Description:** Alliance Imaging, Inc. and Lawrence & Memorial Hospital ("Applicants") propose to establish a mobile Positron Emission Tomography ("PET") scanning service at a total proposed capital expenditure of \$1,295,000. The proposed service will be operated at Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, Connecticut.

**Nature of Proceedings:** On June 4, 2002, the Office of Health Care Access (“OHCA”) received the Applicants’ Certificate of Need (“CON”) application seeking authorization for the establishment of a mobile PET scanning service at a total proposed capital expenditure of \$1,295,000. The proposed service will be operated at Lawrence & Memorial Hospital. The Applicants are health care facilities or institutions as defined in Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

On June 4, 2002, 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. Notices to the public were published in *The Day* (New London), and *The Northeast Minority News*, pursuant to Section 19a-643-45 of OHCA’s Regulations. OHCA received no comments concerning the Applicants’ request for waiver of public hearing during the public comment period. Therefore, on June 20, 2002, 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

Each finding of fact included in this Final Decision has been taken from the CON application and related CON filings. A source reference is included with each finding of fact. All CON applicants must attest to the accuracy and correctness of the information submitted to OHCA as part of the CON application process.

### Clear Public Need

#### **Contribution of the Proposal to the Accessibility of Health Care Delivery in the Region Contribution of the Proposal to the Quality of Health Care Delivery in the Region**

1. Lawrence & Memorial Hospital (“Hospital”) is an acute care hospital located in New London, Connecticut. (*April 12, 2002, CON Application, page 5*)
2. Alliance Imaging, Inc. (“Alliance”) is a company that provides diagnostic imaging and therapeutic systems and related technical support services, as well as management services, to hospitals and other health care providers. (*May 30, 2002, Completeness Responses, page 49*)
3. The Applicants propose to establish PET scanning services at the Hospital; currently there are no PET services at the Hospital. (*December 4, 2001, Letter of Intent, page 5*)
4. Alliance will be responsible for providing PET services at the Hospital on a mobile basis. (*December 4, 2001, Letter of Intent, page 6*)

5. PET is a highly specialized imaging technique that uses positron-emitting radio-pharmaceuticals, or tracers, to produce three-dimensional images allowing physiological processes to be identified, measured, and followed. PET looks at the metabolic activity or body function rather than at anatomy or body form. *(April 12, 2002, CON Application, page 6)*
6. Unlike traditional nuclear medicine, PET uses the tracers to reveal more about the cellular-level metabolic status of a disease than other imaging modalities. *(April 12, 2002, CON Application, page 6)*
7. The primary application of PET imaging is the detection and staging of various cancer types. *(April 12, 2002, CON Application, page 6)*
8. The Hospital's service area consists of East Lyme, Lyme, Old Lyme, Groton, Ledyard, Montville, New London, North Stonington, Salem, Stonington, and Waterford. *(The Health of Connecticut's Hospitals, page 165)*
9. Currently, there are four PET scanners operating in Connecticut:
  - A fixed unit at Veterans Affairs Connecticut Health Care System in West Haven.
  - A mobile unit operated by InSight Health Corporation at the Hospital of St. Raphael, MidState Medical Center, New Britain General Hospital, St. Mary's Hospital, and Waterbury Hospital.
  - A mobile unit operated by InSight Health Corporation at Hartford Hospital, University of Connecticut – John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital, and Windham Community.
  - A mobile unit operated by Alliance at Bristol Hospital, Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, St. Francis Hospital and Medical Center, and William W. Backus Hospital.*(April 12, 2002, CON Application, page 11)*
10. On June 7, 2001, OHCA, under Docket Number 00-509, agreed on a settlement with the Fairfield County PET Consortium, allowing the following six hospitals to establish mobile PET scanning services: Bridgeport, Danbury, Greenwich, Norwalk, St. Vincent's, and Stamford. *(June 7, 2001, Docket Number 00-509)*
11. On May 16, 2002, OHCA, under Docket Number 01-556, approved Hartford Hospital's application to establish a new service, Position Emission Tomography – Computerized Tomography (“PET-CT”) at 80 Seymour Street, Hartford. *(May 16, 2002, Docket Number 01-556)*
12. The Applicants state that the implementation of the new PET services will not affect the existing providers. Most cancer patients are sick and should not travel any great distance. Currently, patients served by the Hospital would most likely travel to New Haven or Hartford to have a PET scan performed. *(April 12, 2002, CON Application, pages 10 and 11)*

13. There are two types of PET scanners: Coincidence PET scanner that utilizes a Gamma Camera, and a Dedicated PET scanner, that provides higher resolution scans. The dedicated PET scanner produces better clinical results and has a much higher sensitivity than coincidence detection. *(April 12, 2002, CON Application, page 8)*
14. The three major areas in which PET scanning is useful are oncology, cardiology, and neurology. *(April 12, 2002, CON Application, pages 6 and 8)*
15. PET is a cost-effective modality due to its impact on clinical decision-making and patient treatment plans. *(April 12, 2002, CON Application, page 9)*
16. The Centers for Medicare and Medicaid Services (“CMS”), formerly the Health Care Financing Administration, implemented broad-based coverage to include diagnosis, staging and re-staging for six types of cancer in December 2000:
  - Lung Cancer
  - Colorectal Cancer
  - Esophageal Cancer
  - Lymphoma
  - Melanoma (not covered for evaluation of regional nodes)
  - Head and Neck Cancers (excluding CNS & thyroid)*(April 12, 2002, CON Application, page 7)*
17. CMS also covers limited diagnostic use for two non-oncological indications: Myocardial Viability, covered following inconclusive SPECT, and Refractory Seizures, covered for pre-surgical evaluation. *(April 12, 2002, CON Application, page 7)*
18. CMS coverage is limited to selected high performance PET scanners only. *(April 12, 2002, CON Application, page 7)*
19. The Applicants developed a need methodology based on the actual volume and types of cancer patients currently treated at each hospital over the past three years. A 60% PET applicable rate for cancer cases and an estimated 50% utilization factor were then applied to each Hospital’s cancer volume. *(May 30, 2002, Completeness Responses, page 15)*
20. In 2000, the population of the Hospital’s service area was 172,258. The statewide rate of cancer cases per 100,000 residents in 1997 was estimated by the Connecticut Department of Public Health to be 551 for all cancer types. Applying the Applicant’s methodology using the state cancer rate, rather than the Hospital’s actual volume, shows the number of potential scans to be:

$$(172,258/100,000) * 551 * .60 * .50 = 284$$

*(Census2000 Connecticut Population by Town and May 30, 2002, CON Completeness Responses, page 59)*

21. The numbers of projected PET scans for the first three years of operation are 19, 287 and 359. *(May 30, 2002, Completeness Responses, page 65)*
22. Alliance has developed a Nuclear/PET Policy and Procedure Manual that the Hospital has indicated it will follow when providing mobile PET scan services at the Hospital. *(April 12, 2002, CON Application, Attachment 8)*
23. In addition to the PET scanner, Alliance will provide the following services:
  - Management Personnel
  - Nuclear Medicine Technologist
  - Operations, Marketing and Customer Support Services
  - Transportation coordinator/driver
  - Hot Lab
  - Provision of film storage media
  - Assistance with patient preparation and transport
  - Operation of the PET scanner
  - Participation in QA programs and utilization review programs*(April 12, 2002 CON Application, Page 18)*

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

24. The proposal has a total capital expenditure of \$1,295,000, which consists of mobile PET Unit, including the van, the hot lab, and software. *(April 12, 2002, CON Application, page 16 and May 30, 2002, Completeness Responses, page 41)*
25. There will be no capital costs for the pad accommodations at the Hospital. The Hospital's existing mobile pad is suitable for the PET scanner mobile van and no changes will be needed. *(May 30, 2002, Completeness Responses, page 4)*
26. Alliance Imaging, Inc. plans on purchasing a GE Standard Advance PET Imaging System using company equity. *(June 4, 2002, CON Application, pages 16 & 638)*
27. The anticipated Medicare reimbursement rate for PET scanning is \$1,850 per scan. *(May 30, 2002, Completeness Responses, page 19)*
28. Alliance will charge the Hospital on a fee per scan basis, dependent on the number of scans performed on a given day. These fees include radiopharmaceuticals. *(May 30, 2002, Completeness Responses, page 41)*

29. The Applicants are projecting incremental increases in operating revenue relating to this project in the years 2002, 2003, and 2004 of \$15,347, \$329,337, and \$422,517, respectively. *May 30, 2002, Completeness Responses, page 65)*

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

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

30. There is no State Health Plan in existence at this time. *(April 12, 2002, CON Application, page 7)*
31. The Applicants have adduced evidence that this proposal is consistent with the Applicants' long-range plan. *(April 12, 2002, CON Application, page 7)*
32. The Applicants have improved productivity and contained costs through energy conservation, application of technology and group purchasing. *(April 12, 2002, CON Application, page 13)*
33. The proposal will not result in changes to the Applicants' teaching and research responsibilities. *(April 12, 2002, CON Application, page 14).*
34. There are no unique patient/physician mix characteristics related to this proposal. *(April 12, 2002, CON Application, page 14)*
35. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate services to the public. *(June 4, 2002, CON Application, Attachments 6 and 9)*

## **Rationale**

Alliance Imaging, Inc. Lawrence & Memorial Hospital (“Applicants”) propose to establish a mobile Positron Emission Tomography (“PET”) scanning service at a total proposed capital expenditure of \$1,295,000. The proposed service will be operated on the campus of Lawrence & Memorial Hospital. PET scanning is an imaging modality for diagnosing neurological, cardiac and oncological conditions. The CMS broad-based coverage includes diagnosis, staging and re-staging for Lung, Colorectal, Esophageal, Head and Neck Cancers, Lymphoma and Melanoma. The Applicants are proposing to use the PET scanner predominantly for oncological purposes.

The Applicant’s project to perform 287 and 359 PET scans for FY2003 and FY2004, respectively. These projections are conservative and appear reasonable.

Alliance Imaging, Inc. has developed procedures and protocols related to the use of the PET scanner. Implementation of the proposal will provide the residents of the Hospital’s service area access to quality PET scanning services. Additionally, as indicated above, PET scanning is an effective imaging modality for diagnosing cancer and managing the treatment and will result in enhanced quality of care.

The anticipated PET scan Medicare reimbursement is \$1,850 per scan. Alliance will charge the Hospital on a fee per scan basis dependent on the number of scans performed on a given day. The Hospital is projecting incremental increases in operating revenues relating to this project for the first three years of operation. The financial projections relating to the operational aspects of this project appear reasonable and achievable.

Based on the foregoing Findings and Rationale, the Certification of Need application of Alliance Imaging, Inc. and Lawrence & Memorial Hospital to establish a mobile Positron Emission Tomography scanning service at the campus of Lawrence & Memorial Hospital is hereby APPROVED.

## Order

The request of Alliance Imaging, Inc. and Lawrence & Memorial Hospital to establish a mobile Positron Emission Tomography (“PET”) scanning service at 365 Montauk Avenue, New London, Connecticut, is approved subject to the following conditions:

1. The authorization shall expire June 20, 2003. Should the Applicant’s project not be completed by that date, the Applicant must seek further approval from OHCA to complete the project beyond that date.
2. The capital cost of the proposal shall be \$1,295,000 and is allocated to Alliance Imaging, Inc. for the acquisition of the mobile PET unit.
3. Alliance Imaging, Inc. shall not exceed the approved capital cost of \$1,295,000. 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.
4. Alliance Imaging, Inc. will provide the service at the campus of Lawrence & Memorial Hospital, 365 Montauk Avenue, New London, Connecticut.
5. The future operating schedule between the Hospital and Alliance Imaging, Inc. shall be established based on joint operating needs and shall be at their discretion.
6. Lawrence & Memorial Hospital in conjunction with Alliance Imaging, Inc. shall file utilization statistics for the PET scanning service on a quarterly calendar 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 mobile PET scanning service commenced operation. The quarterly reports shall include the following:



- Total number of scans scheduled for the PET scanning service;
- Total number of scans performed by the PET scanning service;
- 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

Date signed:  
June 21, 2002

Signed by:  
Raymond J. Gorman  
Commissioner