



Office of Health Care Access Certificate of Need Application

Final Decision

Applicants: Alliance Imaging, Inc.
Bristol Hospital, Inc.
Charlotte Hungerford Hospital
Griffin Hospital
Milford Hospital
New Milford Hospital, Inc.
St. Francis Hospital and Medical Center
William W. Backus Hospital

Docket Number: 01-509

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

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

Filing Date: September 20, 2001

Hearing: Waived

Decision Date: November 20, 2001

Default Date: December 17, 2001

Staff: Maryann Lewis
Laurie Greci

Project Description: Alliance Imaging, Inc., Bristol Hospital, Inc., Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, Inc., St. Francis Hospital and Medical Center, and William W. Backus Hospital (“Applicants”)

propose to establish a mobile Positron Emission Tomography (“PET”) scanning service, at a total proposed capital expenditure of \$2,002,778. The proposed service will be operated at Bristol Hospital, Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, St. Francis Hospital and Medical Center, and William W. Backus Hospital.

Nature of Proceedings: On September 20, 2001, 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 \$2,002,778. The proposed service will be operated at Bristol Hospital, Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, St. Francis Hospital and Medical Center, and William W. Backus Hospital. The Applicants are health care facilities or institutions as defined in Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

On September 24, 2001, 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 Hartford Courant* and *The Norwich Bulletin* on September 28, 2001, in *The Bristol Press* and *The Register Citizen* (Torrington) on September 29, 2001, and in *The Connecticut Post* (Bridgeport), *The New Haven Register*, and *The News Times* (Danbury) on September 30, 2001, 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 October 23, 2001, OHCA granted the Applicants’ request for waiver of the public hearing.

OHCA’s authority to review and approve, modify or deny this application is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Findings of Fact

Clear Public Need

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. Bristol Hospital, Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, St. Francis Hospital and Medical Center, and William W. Backus Hospital (“Applicant Hospitals”) are acute care hospitals located in Bristol, Torrington, Derby, Milford, New Milford, Hartford, and Norwich, respectively. (*May 30, 2001, 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 20, 2001, CON Application, page 594)*
3. Alliance will be responsible for providing PET services at each Applicant Hospital campus on a mobile basis. *(February 1, 2001, Letter of Intent, page 7)*
4. PET is a highly specialized imaging technique that uses short-lived radioactive substances to produce three-dimensional colored images. PET looks at the metabolic activity or body function rather than at anatomy or body form. *(May 30, 2001, CON Application, page 209)*
5. Unlike traditional nuclear medicine, PET uses positron-emitting radiopharmaceuticals, or tracers, revealing more about the cellular-level metabolic status of a disease than other imaging modalities. PET images provide physicians with unique diagnostic information that may alter patient management and reduce the total cost of patient care. *(May 30, 2001, CON Application, page 6)*
6. The primary application of PET imaging is the detection and staging of various cancer types. *(May 30, 2001, CON Application, page 6)*
7. Currently, there are three PET scanners operating in Connecticut:
 1. A fixed unit at Veterans Affairs Connecticut Health Care System in West Haven.
 2. A mobile unit operated by Hospital of St. Raphael, Mid-State Medical Center, New Britain General Hospital, St. Mary’s Hospital, and Waterbury Hospital.
 3. A mobile unit operated by Hartford Hospital, University of Connecticut – John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital, and Windham Community. The unit became operational on September 18, 2001. *((May 30, 2001, CON Application, page 6 and November 9, 2001, Personal Communication with InSight Health Services Corporation)*
8. 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)*
9. 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. *(May 30, 2001, CON Application, page 8)*
10. The three major areas in which PET scanning is useful are oncology, cardiology, and neurology. *(May 30, 2001, CON Application, page 8)*

11. PET is a cost-effective modality due to its impact on clinical decision-making and patient treatment plans. *(May 30, 2001, CON Application, page 9)*
12. In December 2000, HCFA announced its National Medicare Coverage Policy Determination for FDG PET. HCFA announced broad-based coverage to include diagnosis, staging and re-staging for six types of cancer: *(May 30, 2001, CON Application, page 7)*
 1. Lung Cancer
 2. Colorectal Cancer
 3. Esophageal Cancer
 4. Lymphoma
 5. Melanoma (not covered for evaluation of regional nodes)
 6. Head and Neck Cancers (excluding CNS & thyroid)
13. HCFA further announced limited diagnostic use for two non-oncological indications: Myocardial Viability, covered following inconclusive SPECT, and Refractory Seizures, covered for pre-surgical evaluation. *(May 30, 2001, CON Application, page 6)*
14. HCFA coverage is limited to selected high performance PET scanners only. *(May 30, 2001, CON Application, page 7)*
15. 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, 2001, CON Application, pages 15 and 16)*
16. The Applicants' need methodology projects the following number of PET scans at each Applicant Hospital: *(May 30, 2001, CON Application, pages 15 and 16)*

Hospital	Year 1 Projections	Year 2 Projections
Bristol	77	130
Charlotte Hungerford	157	196
Griffin	92	115
Milford	63	78
New Milford	121	151
Saint Francis	483	603
William W. Backus	184	230
Total	1,178	1,505

17. The projected annual number of operating days for the mobile PET scanning service at each Applicant Hospital is as follows: *(August 7, 2001, responses, page 6)*

	Bristol	Hgrfd	Grfn	Milfd	New Milfd	St. Franc	Backus
PET Scans Yr 1	77	157	92	63	121	483	184
Annual Operating Days	26	26	52	26	52	104	52
Average PET Scans/Day	1.5	6	1.7	2.4	2.3	4.6	3.5

(This schedule may vary in response to actual patient volume.)

18. The estimated scan time for each PET scan varies from one hour for brain to three hours for whole body. *(August 7, 2001, Responses, page 9)*
19. Alliance has developed a Nuclear/PET Policy and Procedure Manual that will be followed when providing mobile PET scan services at each Applicant Hospital. *(May 30, 2001, CON Application, Attachment 8)*
20. In addition to the PET scanner, Alliance will provide the following services:

1. Management Personnel
 2. Nuclear Medicine Technologist
 3. Operations, Marketing and Customer Support Services
 4. Transportation coordinator/driver
 5. Hot Lab
 6. Provision of film storage media
 7. Assistance with patient preparation and transport
 8. Operation of the PET scanner
 9. Participation in QA programs and utilization review programs
- (May 30, 2001 CON Application, Page 22)*

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

21. The proposal has a total capital expenditure of \$2,002,778, which consists of mobile PET Unit, including the van and the hot lab. *(June 15, 2001, CON Application, page 113)*
22. There will be no capital costs for the pad accommodations at the seven Applicant Hospitals. The existing MRI pads are suitable for the PET scanner mobile van and no changes will be needed. *(August 7, 2001, Response, page 4)*
23. Alliance Imaging, Inc. plans on purchasing a GE Standard Advance PET Imaging System using company equity. *(May 30, 2001, CON Application, page 20)*

24. The anticipated Medicare reimbursement rate for PET scanning is \$2,576 per scan. *(May 30, 2001, CON Application, page 24)*
25. Alliance will charge the Applicant Hospitals with a service agreement¹ on a fee per scan basis. The charge per PET scan for scans 1 through 6 is \$1,300, the charge for scans 7 and greater is \$1,100 per PET scan. These fees include radiopharmaceuticals. *(May 30, 2001, CON Application, page 794)*
26. Milford Hospital and William Backus Hospital are providing the PET scan service through Alliance under a Lease/Space contract. Alliance Imaging will bill directly for the PET services performed at these Hospitals. Both Hospitals will receive rental income from Alliance. *(August 7, 2001, Response, pages 2)*
27. The Applicants are projecting incremental increases in operating revenue relating to this project in the years 2002 and 2003 as follows: *(May 30, 2001, CON Application, Attachment 12, August 31, 2001, Responses, pages 3,4, and 7, and September 20, 2001, Letter from Christopher Hartley)*

Hospital	2002	2003
Bristol	\$ 83,288	\$102,451
Charlotte Hungerford	35,780	35,471
Griffin	49,756	62,525
Milford	48,000	48,000
New Milford	149,574	154,061
Saint Francis	450,797	604,534
William W. Backus	28,977	27,710

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.:

28. There is no State Health Plan in existence at this time.
29. The Applicants have adduced evidence that this proposal is consistent with the Applicants' long-range plan. *(May 30, 2001, CON Application, page 7)*
30. The Applicants have improved productivity and contained costs through energy conservation, reengineering, application of technology and group purchasing. *(May 30, 2001, CON Application, page 16)*

¹ These Hospitals include Bristol, Charlotte Hungerford, Griffin, New Milford, and St. Francis

31. The proposal will not result in changes to the Applicants' teaching and research responsibilities. *(May 30, 2001, CON Application, page 17).*
32. There are no unique patient/physician mix characteristics related to this proposal. *(May 30, 2001, CON Application, page 17)*
33. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate services to the public. *(May 30, 2001, CON Application, Attachments 6 and 9)*

Rationale

Alliance Imaging, Inc., Bristol Hospital, Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, St. Francis Hospital and Medical Center, and William W. Backus Hospital ("Applicants") propose to establish a mobile Positron Emission Tomography ("PET") scanning service at a total proposed capital expenditure of \$2,002,778. The proposed service will be operated at the campuses of Bristol Hospital, Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, St. Francis Hospital and Medical Center, and William W. Backus Hospital. PET scanning is an imaging modality for diagnosing neurological, cardiac and oncological conditions. HCFA's 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 Applicants developed a need methodology based on the actual volume and types of cancer for which their patients have received treatment. The population, from which the estimates of PET scan volumes were developed, included patients referred by their physicians for diagnosis and treatment at the seven hospitals collaborating to introduce this technology. The methodology projected 1,178 and 1,505 PET scans for the first two years of operation, respectively.

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 Applicant Hospitals' primary service areas access to quality PET scanning services. Additionally, as indicated above, PET scanning is an effective imaging modality for diagnosing and managing treatment and will result in enhanced quality of care.

The anticipated PET scan Medicare reimbursement is \$2,576 per scan. Alliance will charge five of the Hospitals on a fee per scan basis of \$1,300 per PET scan for scans 1 through 6 and \$1,100 per PET scan for scans 7 and greater. Two Hospitals have a retail agreement with Alliance and will receive revenue in the form of rental fees. Each of the seven Applicant Hospitals is projecting incremental increases in operating revenues relating to this project for

the first two 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., Bristol Hospital, Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, St. Francis Hospital and Medical Center, and William W. Backus Hospital (“Applicants”) to establish a mobile Positron Emission Tomography (“PET”) scanning service at each of the Applicant Hospitals is hereby APPROVED.

Order

The request of Alliance Imaging, Inc., Bristol Hospital, Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, St. Francis Hospital and Medical Center, and William W. Backus Hospital to establish a mobile Positron Emission Tomography (“PET”) scanning service is approved subject to the following conditions:

1. The authorization shall expire November 20, 2002. 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 \$2,002,778 and is allocated to Alliance Imaging, Inc. for the acquisition of the mobile PET unit.
3. The Applicants shall not exceed the approved capital cost of \$2,002,778. 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 campuses of Bristol Hospital, Charlotte Hungerford Hospital, Griffin Hospital, Milford Hospital, New Milford Hospital, St. Francis Hospital and Medical Center, and William W. Backus Hospital.
5. The future operating schedule between the Applicant Hospitals and Alliance Imaging, Inc. shall be established based on joint operating needs and shall be at their discretion.

6. Alliance Imaging, Inc. shall file utilization statistics for the PET scanning service for each Applicant Hospital 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 by site:

- 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

Raymond J. Gorman
Commissioner