



Office of Health Care Access Certificate of Need Application

Final Decision

Applicants: InSight Health Services Corporation
Hartford Hospital
University of Connecticut - John Dempsey Hospital
Middlesex Hospital
Manchester Memorial Hospital
Windham Community Memorial Hospital

Docket Number: 01-515

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 28, 2001

Hearing: Waived

Decision Date: August 1, 2001

Default Date: September 26, 2001

Staff: Maryann Lewis

Project Description: InSight Health Services Corporation, Hartford Hospital, University of Connecticut - John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital and Windham Community Memorial Hospital (“Applicants”) propose to establish a mobile Positron Emission Tomography (“PET”) scanning service, at a total proposed capital expenditure of \$2,177,014. The proposed service will be operated at the campus of University of Connecticut - John Dempsey Hospital, Middlesex Hospital,

Manchester Memorial Hospital and Windham Community Memorial Hospital, and at Hartford Hospital's satellite wellness centers located in Avon and Wethersfield.

Nature of Proceedings: On June 28, 2001, the Office of Health Care Access ("OHCA") received the Applicants' Certificate of Need ("CON") application seeking authorization for the establishment a mobile PET scanning service at a total proposed capital expenditure of \$2,177,014. The proposed service will be operated at the campus of University of Connecticut - John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital and Windham Community Memorial Hospital, and at Hartford Hospital's satellite wellness centers located in Avon and Wethersfield. The Applicants are health care facilities or institutions as defined in Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

The Applicants requested a waiver of public hearing pursuant to Section 19a-643-45 of OHCA's Regulations and claimed that the CON application was non-substantive as defined in Section 19a-643-95(3) of OHCA's Regulations. A notice to the public was published on July 16, 2001, in *The Chronicle* (Willimantic), *The Hartford Courant*, *The Journal Inquirer* (Manchester), and *The Middletown Press*. OHCA received no comments concerning the Applicants' request for waiver of public hearing during the public comment period and therefore, on July 31, 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. Hartford Hospital, University of Connecticut ("UConn") - John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital and Windham Community Memorial Hospital ("Applicant Hospitals") are acute care hospitals located in Hartford, Farmington, Middletown, Manchester, and Willimantic, respectively. (*March 14, 2001, Letter of Intent Project Description*)
2. InSight Health Services Corporation ("InSight") is a national imaging technology service company that provides mobile and fixed imaging services, including PET scanning, to hospitals and other health care facilities. (*June 15, 2001, CON Application, page 14*)

3. UConn - John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital and Windham Community Memorial Hospital are proposing to offer the PET scanning service at their campuses. Hartford Hospital is proposing to offer the PET scanning service at the two satellite wellness centers, located in Avon and Wethersfield, Connecticut. *(March 14, 2001, Letter of Intent)*
4. Hartford Hospital is proposing the mobile PET services at the wellness centers in Avon and Wethersfield to increase accessibility for patients and accommodate the mobile technology at minimal cost. *(June 15, 2001, CON Application, page 77 and June 28, 2001 Applicants' responses.)*
5. PET scanning is an imaging modality for diagnosing neurological, cardiac and oncological conditions that has been used mostly as a research tool. *(March 14, 2001, Letter of Intent Project Description)*
6. PET scanning is a non-invasive, diagnostic imaging technique that measures metabolic activity of cells in the human body, providing 10% to 20% more accurate detection and staging over conventional approaches of cancer detection. Images obtained from PET scans also improve patient management in 15% to 30% of all cancer cases. *(June 15, 2001, CON Application, page 14)*
7. There are two types of PET scanners, a Dedicated PET scanner and a Coincidence PET scanner. The Coincidence PET scanner utilizes a Gamma Camera, while the Dedicated PET scanner, which provides higher resolution scans, is composed of multiple rings of detectors stacked one next to another to detect positrons. The Applicants' proposal will utilize the Dedicated PET scanner. *(June 15, 2001, CON Application, page 27)*
8. Hartford and Middlesex Hospitals have been performing PET procedures at their campuses using coincidence PET imaging. The coincidence detection PET imaging will remain available pending final reimbursement decisions by the Health Care Financing Administration ("HCFA"). *(June 15, 2001, CON Application, page 12)*
9. Currently, the only dedicated PET scanner in Connecticut is located at the Veterans Affairs ("VA") Connecticut Health Care System in West Haven. This dedicated PET scanner is primarily a research unit but is sometimes used clinically for patients of Yale-New Haven Hospital and the VA Hospital. *(March 14, 2001, Letter of Intent Project Description)*
10. Mobile PET technology is scheduled to be available in 2001 at eleven hospitals located in central, south central and southwestern Connecticut as authorized under Docket Numbers 00-541 and 00-509. *(June 15, 2001, CON Application, page 35)*

11. In 1998 and 1999, HCFA announced coverage for PET scanning in the following five areas of cancer evaluation and staging: (*March 14, 2001, Letter of Intent Project Description*)
- Evaluation of solitary pulmonary nodules;
 - Initial staging of non-small cell lung carcinomas;
 - Evaluation of recurrent colorectal cancer in patients with rising carcinoembryonic antigen (“CEA”);
 - Staging and restaging of Hodgkin’s and non-Hodgkin’s lymphoma; and
 - Evaluation of recurrent metastatic melanoma.
12. On December 15, 2000, HCFA expanded its national coverage policy of the previously mentioned clinical conditions to include diagnosis as well as adding coverage of two more cancers:
- Head and neck (excluding CNS and thyroid)
 - Esophageal
- HCFA also added coverage for pre-surgical evaluation of refractory seizures and to determine myocardial viability with an inconclusive SPECT study. Additional coverage for breast cancer and dementia was referred to the Medicare Advisory Committee. (*March 14, 2001, Letter of Intent Project Description*)
13. The Applicants are focusing the use of the PET scanner for oncological purposes only at this time, and indicated that the use of PET scanning for neurology is still experimental and that it is cost prohibitive for cardiology. (*June 15, 2001, CON Application, page 16*)
14. Eighty percent (80%) of the 1998 Connecticut cancer deaths were in the three categories of cancer listed below that are the focus for the proposed mobile PET service and for which PET has been shown to be particularly effective. (*June 15, 2001, CON Application, page 18*)

ICD-9 Code	Description	% of Deaths in CT
140-20	Malignant Neoplasm	59%
162	Lung Cancer	15%
153-154	Colorectal	6%

15. The American Cancer Society projections for 1999 showed that at least 32% of new cancer cases in Connecticut would have reimbursable PET scanning as an option in their diagnosis and treatment. (*June 15, 2001, CON Application, page 20*)
16. Focusing on the combined Applicant Hospitals’ primary service area towns and using the cancer incident factor of .0045 (Total population of the towns multiplied by the incident factor, as provided by the American Cancer Society), the Applicants projected on average 4,927 total new cancer cases each year. (*June 15, 2001, CON Application, page 28*)

17. The 4,927 estimated new cancer cases are projected as follows: *(June 15, 2001, CON Application, page 29)*

Cancer Sites	Estimated New Cases
Female Breast	1,423
Prostate	1,423
Lung	547
Colorectal	657
All other	877
Total	4,927

18. The Applicants developed a need methodology based on the actual volume and types of cancer patients currently treated at each hospital. The population from which the estimates of volume were developed were already patients referred by their physicians for diagnosis and treatment at the five hospitals collaborating to introduce this technology. *(June 15, 2001, CON Application, page 31)*

19. The Applicants' need methodology projects the following number of PET scans at each Applicant Hospital: *(June 15, 2001, CON Application, page 36)*

Hospital	Year 1	Year 2	Year 3
Hartford Hospital	451	720	792
UConn John Dempsey Hospital	207	332	366
Middlesex Hospital	194	286	315
Manchester Memorial Hospital	229	328	361
Windham Community Memorial Hospital	62	96	105
Total	1,143	1,762	1,938

20. The scan time for each PET scan varies from 15 minutes for a brain scan to one hour for a full body scan. *(June 15, 2001, CON Application, page 71)*

21. The projected annual number of operating days for the mobile PET scanning service at each Applicant Hospital is as follows: *(June 15, 2001, CON Application, page 37)*

	Hart	UConn	Midsx	Manch	Windham
PET Scans Yr 1	451	207	194	229	62
Annual Operating Days	104	36	52	52	12
Average PET Scans/Day	4	6	4	4	5

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

22. Each Applicant Hospital has agreed to develop and adopt consistent PET protocols. *(June 15, 2001, CON Application, page 47 and Exhibit 12)*

23. InSight and each of the Applicant Hospitals have developed the following procedures: *(June 15, 2001, CON Application, page 47)*

- a. Patient transport to the mobile PET unit. (*Appendix W*)
- b. Handling radioactive spills. (*Appendix U*)
- c. Disposal of unused radioactive material. (*Appendix X*)
- d. InSight's Handling of Radioactive Spills and Disposal of Radioactive Material and Unused Patient Doses. (*Appendix Y*)

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 \$2,177,014, which consists of the following: (*June 15, 2001, CON Application, page 113*)

Description	Cost
Mobile PET Unit Including Van and Hot Lab	\$1,967,614
Pad and Associated Expenses-Hartford Hospital	0
Pad and Associated Expenses-Middlesex Hospital	124,400
Pad and Associated Expenses-UConn – John Dempsey Hospital	500
Pad and Associated Expenses-Manchester Memorial Hospital	34,500
Pad and Associated Expenses-Windham Community Memorial Hospital	50,000
Total	\$2,177,014

25. Each Applicant Hospital will fund the costs for mobile pads and associated renovations through equity contributions. The PET scanner will be acquired through a lease financing arrangement. (*June 15, 2001, CON Application, page 4*)
26. The anticipated Medicare reimbursement rate for PET scanning is \$2,576 per scan. (*June 15, 2001, CON Application, page 70 and Appendix AH*)
27. InSight will charge each Applicant Hospital on a fee per scan basis. The charge per PET scan for scans 1 through 5 is \$750, the charge for scans 6 through 7 is \$600 per PET scan, and the charge for scan 8 and greater is \$475 per PET scan. (*June 15, 2001, CON Application, page 70*)
28. FDG costs were estimated at \$450 per scan based on the best estimate of market. (*June 15, 2001, CON Application, page 70*)
29. Gross charges per scan were set at \$3,500 per scan. (*June 15, 2001, CON Application, page 70*)

30. Each hospital will bill for the technical fee. That fee includes the FDG radioisotope used in a PET scan. *(June 15, 2001, CON Application, page 55)*
31. The Applicants are projecting incremental increases in operating revenue relating to this project for the first three years of operation as follows: *(June 15, 2001, CON Application, page 68 and Exhibit 15)*

Hospital	Year 1	Year 2	Year 3
Hartford Hospital	\$590,273	\$953,232	\$1,047,679
UConn - John Dempsey Hospital	270,901	444,046	477,970
Middlesex Hospital ¹	183,981	344,576	367,843
Manchester Memorial Hospital	285,439	400,372	428,320
Windham Community Memorial Hospital	78,208	107,785	122,828

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.:

32. There is no State Health Plan in existence at this time. *(June 15, 2001, CON Application, page 13)*
33. The Applicants have adduced evidence that this proposal is consistent with the Applicants' long-range plan. *(June 15, 2001, CON Application, page 13)*
34. The Applicants have improved productivity and contained costs through energy conservation, reengineering, application of technology and group purchasing. *(June 15, 2001, CON Application, page 49)*
35. The proposal will not result in changes to the Applicants' teaching and research responsibilities. *(June 15, 2001, CON Application, page 52)*
36. The unique patient/physician mix characteristics related to this proposal are nuclear medicine programs and oncology programs. *(June 15, 2001 CON Application, page 52)*
37. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate services to the public. *(June 15, 2001, CON Application, pages 41-42, Exhibits 2 and 11, Appendixes N and O)*

¹ Year 1 represents nine months of activity

Rationale

InSight Health Services Corporation, Hartford Hospital, University of Connecticut - John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital and Windham Community Memorial Hospital (“Applicants”) propose to establish a mobile Positron Emission Tomography (“PET”) scanning service at a total proposed capital expenditure of \$2,177,014. The proposed service will be operated at the campus of University of Connecticut - John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital and Windham Community Memorial Hospital, and at Hartford Hospital’s satellite wellness centers located in Avon and Wethersfield. PET scanning is an imaging modality for diagnosing neurological, cardiac and oncological conditions. The PET scanner measures the metabolic activity of cells in the human body and provides 10% to 20% more accurate detection and staging over conventional approaches of cancer detection. Images obtained from PET scanning also improve patient management in 15% to 30% of all cancer cases. PET scanning has primarily been used as a research tool because reimbursement from the Health Care Financing Administration (“HCFA”) was not available. In 1998 and 1999, HCFA announced coverage for the following five areas of cancer evaluation and staging: evaluation of solitary pulmonary nodules; initial staging of non-small cell lung carcinomas; evaluation of recurrent colorectal cancer in patients with rising carcinoembryonic antigen (“CEA”); staging and restaging of Hodgkin’s and non-Hodgkin’s lymphoma; and evaluation of recurrent metastatic melanoma. On December 15, 2000, HCFA expanded its national coverage policy of the previously mentioned clinical conditions to include diagnosis as well as adding coverage of head and neck (excluding CNS and thyroid) and esophageal. HCFA also added coverage for pre-surgical evaluation of refractory seizures and to determine myocardial viability with an inconclusive SPECT study. Additional coverage for breast cancer and dementia was referred to the Medicare Advisory Committee. The Applicants are proposing to use the PET scanner for oncological purposes only.

The Applicants developed a need methodology based on the actual volume and types of cancer patients currently treated at each hospital. The population from which the estimates of volume were developed were already patients referred by their physicians for diagnosis and treatment at the five hospitals collaborating to introduce this technology. The methodology projected 1,143, 1,762, and 1,938 PET scans for the first three years of operation, respectively. The Applicants provided another methodology that projected on average 4,927 total new cancer cases each year². The American Cancer Society projections for 1999 showed that at least 32% of new cancer cases in Connecticut would have reimbursable PET scanning as an option in their diagnosis and treatment. Both of these need methodologies demonstrate a need for PET scanning within the Applicants’ primary service area.

² Calculated using the total population of the primary service area towns multiplied by the incident factor of .0045, as provided by the American Cancer Society.

The Applicants have developed uniform procedures and protocols related to the use of the PET scanner. The procedures address both clinical and safety issues such as patient transport, handling of radioactive spills, and disposal of unused radioactive material. 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 more accurate in detecting cancers and managing treatment and will result in enhanced quality of care.

The anticipated PET scan Medicare reimbursement is \$2,576 per scan. InSight will charge each Hospital on a fee per scan basis of \$750 per PET scan for scans 1 through 5 and \$600 per PET scan for scan 6 and 7, and \$475 for scan 8 and greater. The Applicant Hospitals are each 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 InSight Health Services Corporation, Hartford Hospital, University of Connecticut - John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital and Windham Community Memorial 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 InSight Health Services Corporation, Hartford Hospital, University of Connecticut - John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital and Windham Community Memorial Hospital to establish a mobile Positron Emission Tomography ("PET") scanning service is approved subject to the following conditions:

1. University of Connecticut - John Dempsey Hospital, Middlesex Hospital, Manchester Memorial, and Windham Community Memorial Hospital are approved to establish a PET scanning service on the campus of each of their hospitals. Hartford Hospital is approved to establish a PET scanning service at the two satellite wellness centers, located in Avon and Wethersfield. InSight Health Services Corporation will provide the service.
2. The authorization shall expire December 31, 2002, unless the Applicants present evidence to OHCA that the mobile PET service is operational by that date.
3. The capital cost of the proposal shall be \$2,177,014 and is allocated as follows:

Price of mobile PET unit plus Van with Hot Lab	\$1,967,614
Hartford Hospital	0
University of Connecticut - John Dempsey Hospital	124,400
Middlesex Hospital	500
Manchester Memorial Hospitals	34,500
Windham Community Memorial Hospital	<u>50,000</u>
Total Approved Capital Expenditure	\$2,177,014

4. The Applicants shall not exceed the approved capital expenditure of \$2,177,014. 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.
5. The future operating schedule between the Hospitals and InSight Health Services Corporation shall be established based on joint operating needs and shall be at their discretion.
6. InSight Health Services Corporation 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

Signed by the Comr. On 8/1/01

Date

Raymond J. Gorman
Commissioner

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