



Office Of Health Care Access Certificate of Need Application

Final Decision

Applicants: InSight Health Corporation, MidState Medical Center, John Dempsey Hospital, and New Britain General Hospital

Docket Number: 05-30562-CON

Project Title: Proposal to Acquire Mobile PET/CT Scanning Service

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

Filing Date: January 23, 2006

Hearing Date: March 23, 2006

Presiding Officer: Cristine A. Vogel

Decision Date: April 18, 2006

Default Date: April 23, 2006

Staff Assigned: Laurie K. Greci

Project Description: InSight Health Corporation, MidState Medical Center, John Dempsey Hospital, and New Britain General Hospital (“Applicants”) propose to acquire a Positron Emission Tomography/Computed Tomography Scanner (“PET/CT”) to replace the existing mobile PET scanning service with mobile PET/CT scanning service, at a total capital expenditure of \$1,509,678.

Nature of Proceedings: On January 23, 2006, the Office of Health Care Access (“OHCA”) received the Certificate of Need (“CON”) application from InSight Health Corporation, MidState Medical Center, John Dempsey Hospital, and New Britain General Hospital (“Applicants”) seeking authorization to acquire a Positron Emission

Tomography/Computed Tomography Scanner (“PET/CT”) to replace the existing mobile PET scanning service with a mobile PET/CT scanning service, at a total capital expenditure of \$1,509,678. MidState Medical Center, John Dempsey Hospital, and New Britain General Hospital are health care facilities or institutions 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 Applicants’ Letter of Intent to file its CON application was published in *The Herald* (New Britain) and *The Record-Journal* (Meriden) on August 10, 2005, and in *The Hartford Courant* on August 12, 2005, pursuant to Sections 19a-638 and 19a-639, C.G.S. OHCA received no responses from the public concerning the Applicants’ Letter of Intent.

Pursuant to Sections 19a-638 and 19a-639, C.G.S., a public hearing regarding the CON application was held on March 23, 2006. On February 17, 2006, the Applicants were notified of the date, time and place of the hearing. A notice to the public was published in *The Herald* (New Britain), *The Record-Journal* (Meriden), and *The Hartford Courant* on February 21, 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 Sections 19a-638 and 19a-639, C.G.S.

OHCA’s authority to review and approve, modify or deny the CON application is established by Sections 19a-638 and 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. InSight Health Corporation (“InSight”), a wholly owned subsidiary of InSight Health Services Holdings Corporation, provides diagnostic imaging, treatment and related management services. Currently, InSight provides mobile positron emission tomography (“PET”) scanning service to three Connecticut hospitals (“Hospitals”):
 - MidState Medical Center, 453 Lewis Avenue, Meriden;
 - John Dempsey Hospital of the University of Connecticut Health Center, 263 Farmington Avenue, Farmington; and
 - New Britain General Hospital, 100 Grand Street, New Britain.*(November 16, 2006, Initial CON Application Submission, pages 356 to 360 and page 428)*
2. MidState Medical Center (“MidState”) and New Britain General Hospital (“NBGH”) were authorized by OHCA to operate a mobile PET scanning service under Docket

Number 00-541 on February 5, 2001. John Dempsey Hospital (“Dempsey”) was authorized by OHCA to operate a mobile PET scanning service under Docket Number 01-515 on August 1, 2001. *(February 5, 2001, Final Decision for Docket Number 00-541 and August 1, 2001, Final Decision for 01-515)*

3. InSight and the Hospitals (“Applicants”) propose to replace the existing mobile PET scanning service with a mobile positron emission tomography and computed tomography (“PET/CT”) scanning service. *(November 16, 2005, Initial CON Application Submission, page 2)*
4. The primary service area for each Hospital is listed in the following table:

Table 1: Primary Service Areas by Town for the Hospitals

Hospital	Primary Service Area by Town
MidState	Cheshire, Meriden, and Wallingford
Dempsey	Avon, Bloomfield, Burlington, Canton, East Hartford, Farmington, Granby, Hartford, New Britain, Newington, Simsbury, and West Hartford
NBGH	Berlin, New Britain, Plainville, and Southington

(November 16, 2005, Initial CON Submission, page 9)

5. MidState is accredited by the American College of Surgeons as a Comprehensive Community Cancer Center that provides diagnosis, treatment, and rehabilitation services. *(November 16, 2005, Initial CON Application Submission, page 3)*
6. Dempsey is the acute care general hospital of the University of Connecticut Health Center (“UCHC”). Dempsey provides comprehensive cardiovascular, cancer, and musculoskeletal services. Cancer services are provided by the Carole and Ray Neag Comprehensive Cancer Center, the outpatient cancer center, as well as the Jean Marie Colbert Cancer Care Inpatient Unit, a floor of the hospital dedicated to inpatient cancer care. The cancer program at Dempsey is accredited by the Commission on Cancer of the American College of Surgeons. *(November 16, 2005, Initial CON Application Submission, page 3)*
7. NBGH provides comprehensive inpatient and outpatient services, including, but not limited to, oncology, cardiology, and endocrinology. The George Bray Cancer Center at NBGH is a center of excellence that provides radiation, chemotherapy and clinical research trial opportunities. The cancer center is accredited by the Commission on Cancer of the American College of Surgeons. *(November 16, 2005, Initial CON Application Submission, page 3)*
8. The current providers of PET/CT scanning within the Applicants’ primary service area include Hartford Hospital, Saint Francis Hospital and Medical Center, and Middlesex Hospital. As each of these hospitals have fixed PET/CT scanning service, the Applicants stated that the existing providers will not be impacted with respect to patient volume, financial stability or quality of care. *(November 16, 2005, Initial CON Application Submission, page 12)*

9. The Applicants based the need to acquire the mobile PET/CT scanning services on the following factors:
- Increasing volumes in PET scans performed;
 - Faster throughput of PET/CT over PET alone;
 - Enhanced imaging that improves staging in tumors of the head and neck;
 - Potential use in radiotherapy planning; and
 - Improved physician and patient satisfaction.

(November 16, 2005, Initial CON Application Submission, pages 6 to 8)

10. The Applicants reported the volumes for the mobile PET scanning service at each Hospital as follows:

Table 2: Volume of Mobile PET Scanning Service

Hospital	FY 2003	FY 2004	FY 2005
MidState	265	314	331
NBGH	276	242	284
Dempsey	176	241	300
Total	717	797	915

NOTE: The data reported by the Applicants could not be verified by OHCA.
(January 23, 2006, Completeness Response, pages 35 and 36)

11. The top three areas for PET scans have been pulmonary and lung, lymphoma, and breast. The majority of the referrals for the Hospital's PET procedures relates to indications for radiation treatment planning and includes PET imaging for:
- Restaging of lymphoma;
 - Restaging of lung carcinoma;
 - Single pulmonary nodules related to lung carcinoma;
 - Staging and restaging of breast cancer;
 - Initial stage of lung cancer; and
 - Diagnosis of colorectal carcinoma.

(January 23, 2006, Completeness Response, page 9)

12. The proposed PET/CT will provide the following qualitative patient care improvements:
- Improved image quality;
 - Improved accuracy in disease staging, surgical planning, and radiation treatment planning;
 - Improved interpreter confidence; and
 - Patient comfort and decrease in motion artifacts due to faster scanning times.

(March 16, 2006, Prefiled Testimony of Judy Erbstein, Area Director of Northeast Operations for InSight)

13. The Applicants' projected PET/CT scan volume for FY 2006 through FY 2008 with the proposed CT scanner is as follows:

Table 3: Projected PET/CT Volume¹ by Hospital

Hospital	FY 2006	FY 2007	FY 2008
MidState	352	403	454
NBGH	316	367	418
Dempsey	379	420	474
Total	1,064	1,217	1,370

NOTE: The data reported by the Applicants could not be verified by OHCA.
(November 16, 2005, Initial CON Application Submission, pages 15 and 16)

14. The Applicants stated that PET/CT is approximately 30% faster than PET alone allowing for higher patient throughput and more comfortable examination and less movement by the patients. With faster scanning times, the average PET/CT scan per patient is forty-five minutes versus one hour on the current PET scanner. Additional patients can be scanned on the same day and staffing costs will remain the same.
(January 23, 2006, Completeness Response, page 2)
15. Gary J Dee, M.D., Chief of Radiology for MidState, testified that:
- The PET service at MidState has grown as the indications for PET service has increased and as the patients and the medical staff have come to understand the need for PET;
 - MidState is currently losing volume to providers of fixed PET/CT scanning service and that the volume loss is not reflected in the volumes reported.
 - Patients are leaving the community to receive a PET/CT in Hartford or New Haven;
 - In partnership with InSight and the other Hospitals, the PET/CT service will be provided in a cost-effective manner by not requiring extra days of service at a minimal cost to the Applicants;
 - Insurance companies will not reimburse PET/CT scans at a higher rate than PET scans;
 - InSight will augment the current software allowing MidState and the other Hospitals to integrate IMRT with the Siemens PET/CT, improving the delivery of radiation to areas of tumor, while sparing areas of normal, health tissue.
- (March 23, 20006, Prefiled Testimony and Hearing Testimony of Dr. Gary Dee)
16. John Vento, M.S, M.D., Assistant Professor for the Department of Imaging and Therapeutics, Division of Nuclear Medicine at Dempsey testified that Dempsey added a second day of imaging to meet demand as patients were obtaining PET scans at other providers. With the PET/CT and the accompanying reduction in scan time, Dempsey can return to a single day of service. (March 23, 20006, Hearing Testimony of Dr. John Vento)

¹ Volume projections were based on the replacement of the PET scanner exclusively with the PET/CT scanner and approved applications for PET/CT scans related to oncology. Volumes for the new and growing indications in the cardiac and neurological areas were not included in the projected volumes.

17. Stephen Strongwater, M.D., Associate Dean for Clinical Affairs, Director of Clinical Operations, and Hospital Director for Dempsey testified that the proposed PET/CT scanner will directly impact a number of the mission-direct programs at the University of Connecticut Health Center. Those programs include medical student teaching, the Neag Cancer Center, the Color Cancer Detection Center, and the Calhoun Cardiology Center. Also, clinical trials frequently require PET/CT studies. *(March 23, 2006, Hearing Testimony of Dr. Stephen Strongwater)*
18. The primary service area populations for each Hospital as well as the expected number of cancers are reported in the following table. The all-invasive cancer rates used to calculate the number of cancers were age-standardized using the age distribution of the total U.S. population in 2000 as the standard populations. The rate for the number of cancers for males is 587.73 per 100,000 males and the rate for females is 441.55 per 100,000 females.

Table 4: Cancer Incidence by Hospital and Primary Service Area Towns

Hospital	Town	Total Male Population	Total Female Population	Total Age-Standardized Male Cancers	Total Age-Standardized Female Cancers	Total Number of Cancers
MidState	Cheshire	15,197	13,346	89	59	148
	Meriden	28,214	30,030	166	133	299
	Wallingford	20,732	22,294	122	98	220
MidState Subtotals		64,143	65,670	377	290	667
Dempsey	Avon	7,579	8,253	45	36	81
	Bloomfield	8,777	10,810	52	48	100
	Canton	4,283	4,557	25	20	45
	East Hartford	23,672	25,903	139	114	253
	Farmington	11,197	12,444	66	55	121
	Hartford	58,071	63,507	341	280	621
	New Britain	34,257	37,281	201	165	366
	Newington	13,778	15,528	81	69	150
	Rocky Hill	8,875	9,091	52	40	92
	Simsbury	11,296	11,938	66	53	119
	West Hartford	29,252	34,337	172	152	324
Dempsey Subtotals		211,037	233,649	1,240	1,032	2,272
NBGH	Berlin	8,847	9,368	52	41	93
	New Britain	34,257	37,281	201	165	366
	Plainville	8,461	8,867	50	39	89
	Southington	19,255	20,473	113	90	203
NBGH Subtotals		70,820	75,989	416	335	752
Hospital Grand Totals		346,000	375,308	2,034	1,657	3,691

(Census 2000 Population by Town for Connecticut and November 16, 2005, Initial CON Application Submission, Appendix II)

19. Each Hospital testified at the hearing that the majority of patients diagnosed with cancer may be referred for a PET/CT scan. At the hearing, the witnesses for the Hospitals affirmed the following information:

Table 5: Estimated Market Share by Hospital

Hospital	Total Number of Estimated Cancers in Primary Service Area Population	Percent Market Share for Oncological Patients	Estimated Number of Cancer Patients
MidState	666	45%	300
Dempsey	2,272	10%	227
NBGH	752	59%	444
Total	3,690	-	971

NOTE: The data reported by the Applicants could not be verified by OHCA.
(March 23, 2006, Hearing Testimony of Dr. Gary Dee for MidState, Monte Giannini for Dempsey, and Dr. Steven Stier for NBGH)

20. Steven Stier, M.D., a radiologist representing NBGH, and Dr. Dee testified that although the faster throughput of the PET/CT scanner would allow a maximum of 15 scans per day, the practical number of patients to schedule for each of mobile service is 12 patients. *(March 23, 2006, Hearing Testimony of Dr. Gary Dee and Dr. Steven)*
21. Each Hospital averages up to eight scans per day for the PET scanning service. However, additional scheduled scans are often not completed due to high blood glucose levels, claustrophobia, or other patient conditions. *(March 23, 2006, Hearing Testimony of Judy Erbstein)*

Financial Feasibility and Cost Effectiveness 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 the Payers for Such Services
Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

22. The total proposed capital expenditure for the proposal is \$1,509,678, the fair market value of the PET/CT scanner, excluding capitalized financial costs of \$98,022. *(November 16, 2005, Initial CON Application Submission, page 23)*
23. InSight will lease from General Electric Healthcare Financial Services a Siemens Biograph-6 PET/CT, mobile coach, and the associated accessories. *(November 16, 2005, Initial CON Application Submission, Appendix VI).*

24. The Hospitals are projecting incremental increases in operating revenue relating to the proposal for the first three years of operation as follows:

Table 6: Projected Increases in Operating Revenue

Hospital	FY 2006	FY 2007	FY 2008
MidState	\$54,000	\$73,000	\$73,000
Dempsey	\$16,034	\$93,284	\$249,229
NBGH	\$43,064	\$85,255	\$90,308

(November 16, 2005, Initial CON Application Submission, pages 418 to 420)

25. There is no State Health Plan in existence at this time. *(November 16, 2005, Initial CON Application Submission, page 2)*
26. The Applicants have adduced evidence that the proposal is consistent with the Applicant's long-range plan. *(November 16, 2005, Initial CON Application Submission, page 2)*
27. The Applicants have improved productivity and contained costs by the application of new technology. *(November 16, 2005, Initial CON Application Submission, page 22)*
28. The proposal will not result in any changes to the Applicants' teaching and research responsibilities. *(November 16, 2005, Initial CON Application Submission, page 22)*
29. The proposal will not result in any change to patient/physician mix of the Applicants. *(November 16, 2005, Initial CON Application Submission, page 22)*
30. The Applicants have sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. *(November 16, 2005, Initial CON Application Submission, Appendix VI)*
31. The Applicants' rates are sufficient to cover the proposed capital cost and operating costs associated with the proposal. *(November 16, 2005, Initial CON Application Submission, pages 418 to 420)*

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.

InSight Health Corporation (“InSight”) began providing mobile PET scanning service to the three hospitals of MidState Medical Center (“MidState”), John Dempsey Hospital of the University of Connecticut Health Center (“Dempsey”), and New Britain General Hospital (“NBGH”) in 2001 under Certificate of Need (“CON”) authorization from the Office of Health Care Access (“OHCA”). Each Hospital has an accredited cancer program to treat their patient population. Since 2003, the PET scanning volumes at each Hospital have increased. The Applicants are proposing to offer mobile PET/CT scanning service in lieu of the mobile PET scanning service.

The Applicants based the need for acquiring the mobile PET/CT scanner on the following factors: increasing volumes of scans performed; the faster throughput allowed by the PET/CT scanner over the PET scanner; the ability to improve the staging of head and neck cancer with the PET/CT scanner; the added benefit of using PET/CT digitized scans as an aid in planning radiotherapy for patients; and the improvement in physician and patient satisfaction. Dempsey, part of the University of Connecticut’s School of Medicine, stated that the PET/CT scans are an important part of their teaching mission to its medical students and staff.

The Hospitals expect that the majority of new cancer patients will be eligible to receive a PET/CT scan for diagnostic, staging, and treatment purposes. Although OHCA cannot verify the current rates of cancer incidence, it appears that each Hospital has an adequate patient population to support the mobile PET/CT service one day per week. Additionally, Dempsey will no longer need the second day of service to meet its demand. OHCA finds that the proposal will improve access to care by increasing patients’ comfort, by accommodating more scans, and by enhancing the specificity and sensitivity of the scan images produced.

The total capital expenditure for the CON proposal is \$1,509,678, which includes the PET/CT scanner, the mobile van, and the associated accessories. Each hospital projects an incremental gain in operating revenue related to the proposal. Although OHCA cannot draw any conclusions, the Hospitals’ volumes and financial projections upon which they are based 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 InSight Health Corporation, MidState Medical Center, John Dempsey Hospital, and New Britain General Hospital for the acquisition of a PET/CT scanner to replace the existing mobile PET scanning service with mobile PET/CT scanning service, at a total capital expenditure of \$1,509,670, is hereby GRANTED.

Order

InSight Health Corporation, MidState Medical Center, John Dempsey Hospital, and New Britain General Hospital (“Applicants”) are hereby authorized to acquire a Positron Emission Tomography/Computed Tomography Scanner (“PET/CT”) to replace the mobile PET scanning service to a mobile PET/CT scanning service, at a total capital expenditure of \$1,509,678, subject to the following conditions:

1. This authorization shall expire on April 18, 2008. Should operation of the PET/ CT scanning service not be completed by that date, the Applicants must seek further approval from OHCA to complete the project beyond that date.
2. The Applicants shall not exceed the approved total capital expenditure of \$1,509,678. In the event that the Applicants learn of potential capital expenditure increases or expects that final project expenditures will exceed those approved, the Applicants shall file with OHCA a request for approval of the revised CON project budget.
3. InSight Health Corporation shall file with OHCA utilization statistics for the mobile PET-CT scanner service at MidState Medical, John Dempsey Hospital, and New Britain General Hospital 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 mobile PET-CT scanner commenced operation. The quarterly reports shall be filed by Hospital and include the following information:
 - Total number of scans scheduled for the mobile PET-CT scanner;
 - Total number of scans performed by the mobile PET-CT 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.
4. This authorization requires that the Applicants’ existing PET scanning service and use of the PET scanner be discontinued upon implementation of the PET/CT scanning service.

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

April 18, 2006

Signed by Cristine A. Vogel
Commissioner

CAV: lkg