Office of Health Care Access

Final Decision

Applicant:	**HealthCenter Imaging, LLC**
Docket Number:	**02-545**
Project Title:	**Establish a Dedicated Cardiac PET-CT Imaging Center**
Statutory Reference:	**Sections 19a-638 & 19a-639, Connecticut General Statutes**
Filing Date:	**March 11, 2003**
Hearing Date:	**April 29, 2003**
Intervenors:	**Radiological Society of Connecticut, Inc.** **Fairfield County Mobile PET Collaborative**
Presiding Officer:	**Mary M. Heffernan, Commissioner**
Decision Date:	**May 20, 2003**
Default Date:	**June 9, 2003**
Staff:	**Kimberly Martone** **Laurie Greci**

Project Description: HealthCenter Imaging, LLC ("Applicant") proposes to establish a dedicated cardiac PET-CT ("position emission tomography - computed tomography") imaging center to be located at 999 Silver Lane in Trumbull, Connecticut, at a total capital cost of $2,861,274.

Nature of Proceedings: On March 11, 2003, the Office of Health Care Access ("OHCA") received the complete Certificate of Need ("CON") application of HealthCenter Imaging, LLC to establish a dedicated cardiac PET-CT imaging center to be located at 999 Silver Lane in Trumbull, Connecticut, at a total capital cost of

$2,861,274. The Applicant is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A public hearing was held on April 29, 2003. The Applicant was notified of the date, time, and place of the hearing and a notice to the public was published prior to the hearing in the *Connecticut Post* in Bridgeport. Commissioner Mary M. Heffernan 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.

The Radiological Society of Connecticut, Inc. petitioned for Party or in the alternative Intervenor Status with the right of cross-examination and was granted Intervenor status with no right of cross-examination in this proceeding. Fairfield County Mobile PET Collaborative petitioned and was granted Intervenor Status with no right of cross-examination in this proceeding.

The Presiding Officer heard testimony from witnesses for the Applicant and Intervenors and in rendering this decision, considered the entire record of the proceeding. OHCA's authority to review, approve, modify or deny this proposal 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 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
Impact on the Applicant's Current Utilization Statistics
Contribution of the Proposal to the Quality and Accessibility of Health Care Delivery in the Region

1. HealthCenter Imaging, LLC ("Applicant") is a limited liability corporation and healthcare information technology services organization with the mission to deliver outsourced information technology solutions to large healthcare organizations. The organization is located at 24 Sturges Common Road in Westport, Connecticut. *(July 22, 2002 Letter of Intent, Project Description and November 13, 2002, CON Application, pages 10 & 79)*

2. The Applicant proposes to establish a dedicated cardiac PET-CT imaging center ("Center") in approximately 2,000 square feet of office space within an existing medical office building at 999 Silver Lane in Trumbull, Connecticut. *(November 13,*

2002, CON Application, page 11 and January 31, 200,3 Completeness Responses, page 135)

3. Integrated PET-CT scanners allow physicians to combine functional information from PET (measures of blood flow, cardiac wall motion, ejection fraction, and metabolism) with detailed anatomical information from CT (atherosclerotic plaque burden measurement and assessment of stenoses of the coronary arteries) for a comprehensive noninvasive diagnosis in a single study. *(November 13, 2002, CON Application, page 1)*

4. Based upon experience at other similar facilities, the Applicant expects that 55% of all scans will be related to diagnosis of ischemic heart disease and 45% will be related to the assessment of ischemia in patients with known coronary heart disease following a coronary intervention, bypass surgery or under medical therapy. *(November 13, 2002, CON Application, page 17)*

5. The principal procedure to be offered is PET-MPI (myocardial perfusion imaging). The Applicant stated that PET is the accepted gold standard for myocardial perfusion and metabolic imaging. *(November 13, 2002, CON Application, page 1)*

6. The primary service area for the proposed Center is Fairfield County. *(November 13, 2002, CON Application, page 1)*

7. The proposed Center would serve a population of more than 1 million residents who reside within less than 20 miles driving distance. *(November 13, 2002, CON Application, page 8)*

8. In Fairfield County, over 90% of all outpatient nuclear cardiology (SPECT) procedures are performed by cardiologists outside of the hospital. *(April 25, 2003, Testimony of Johan Brag)*

9. PET has numerous advantages over SPECT[1] including higher sensitivity and resolution, improved specificity, and the ability to detect coronary artery disease ("CAD") at an earlier stage through quantification of blood flow reserve. *(November 13, 2002, CON Application, page 33)*

10. The high accuracy, speed and convenience of PET-CT have the potential of turning the modality into the standard of care for the early detection of heart disease and for the selection and monitoring of therapy. *(November 13, 2002, CON Application, page 4)*

11. The Applicant based the need for the PET-CT scanner on the following:
    - Projected growth in the demand for PET-CT and MPI services in the primary service area due to aging of the population and technology advances;

[1] SPECT, or single photon computed tomography, is a noninvasive radiological technique that uses a radionuclide tracer to provide a three-dimensional image of an organ's anatomy and function. *(www.heartcenteronline.com)*

- Scheduling backlogs at physician-office based cardiac imaging facilities; and
- Projected referrals by service area physicians to the Center.

(November 13, 2003, CON Application, pages 4 and 6 and January 31, 2003, Completeness Response, pages 134 and 138)

12. The prevalence of chronic heart disease in Connecticut is 80 per 1,000 persons between 45 and 55 years of age, 200 per 1,000 for persons between 55 and 65, 273 per 1,000 persons between 65 and 74 and 371 per 1,000 persons over the age of 75. *(November 13, 2002, CON Application, page 26)*

13. The Applicant provided a target market opportunity analysis based on the specific incidence of various clinical indications where it has been demonstrated that PET provides clear evidence of superior patient management over SPECT. The following table presents those indications and the number of Connecticut residents that meet one of the criteria[2] for making PET MPI a first line test for diagnosis of CAD:

Table 2: Target Market Opportunity Based on Specific Disease Incidence

Selected Clinical Indication	Prevalence	Incidence
CAD Assessment in patients with chronic angina	83,200	
Obese Patients		5,000
Women		2,500
Elderly		10,000
CAD Diagnosis in Asymptomatic Patients		
Type 2 Diabetics		10,400
Preoperative Risk Assessment		
Kidney or Pancreas Transplant		1,500
Vascular Surgery Clearance		1,500
Acute Coronary Artery Disease	97,500	
Myocardial Infarction		6,500
Unstable Angina		7,300
Intervention Staging and Follow-up		
Percutaneous Coronary Intervention		8,366
Coronary Artery Bypass Graft Surgery		6,175
Heart Failure	62,400	5,200
Total		**86,941**

(November 13, 2002, CON Application, page 43 and January 31, 2002, Completeness Response, page 136)

14. The target market opportunity for the Center is approximately 3,800 patients.

87,000 * 0.15 * 0.29 = **3,800 patients.**

This market opportunity is based on the following:

- A 15% market penetration of the 87,000 patients identified above.

[2] Patients that have more than one qualifying condition are <u>not</u> counted twice.

- A population representing 29% of the total state population (1,000,000/3,405,565).

(November 13, 2002, CON Application, pages 43, 46, and 47)

15. Based on 400 annual MPI referrals per cardiologist and 25-40% of these MPI referrals for PET-MPI, the Applicant projects the following procedure volume by indication for the first four fiscal years of operation of the Center:

Table 3: Utilization Projections*

Total Scans	**2004**	**2005**	**2006**	**2007**
Cardiac Metabolism	500	750	1000	1250
Cardiac Perfusion	2000	2500	3000	3500
Total	**2500**	**3250**	**4000**	**4750**
PET MPI exams/day	8	10	12	14
PET FDG exams/day	2	3	4	5

* The projected volumes do not include separate referrals from internal medicine physician practices such as PRIMED and other cardiology groups in the service area.

(November 13, 2002, CON Application, page 9 and April 24, 2003, Responses to Interrogatories, page 4)

16. There is currently an average two-week backlog for SPECT imaging in Fairfield County. *(November 13, 2002, CON Application, page 6)*

17. The Applicant stated that currently patients are either tested with less accurate techniques or referred to facilities in New York City. *(November 13, 2002, CON Application, page 6)*

18. The Applicant provided a Medical Services Agreement between HealthCenter Imaging, LLC and Cardiac Specialists, P.C. ("Practice"), which consists of 11 cardiologists, including 6 Board Certified in Nuclear Cardiology and 4 certified in Invasive Cardiology, for the provision of PET services to the Center. The Practice will supervise at least 1,000 cardiac PET exams for patients booked by the Center. The Practice will designate a Medical Director to assume medical accountabilities for all PET services. The Practice will retain all decision-making authority regarding the selection of any of its patients for referral to the Center. *(January 31, 2003, Completeness Responses, Exhibit L and April 24, 2003, Responses to Interrogatories, page 10)*

19. Physician supervision will be provided within the Center at all times to ensure patient safety. Most interpretations will be performed remotely by board-certified nuclear cardiologists typically operating from their respective offices. Onsite presence of the interpreting physician is not required. Since the Center and the Practice share a common building, physicians will most likely be available onsite for interpretations. *(April 24, 2003, Responses to Interrogatories, page 200)*

20. All decisions regarding testing will be made by the referring physician prior to referral to the Center. The Center will help verify eligibility with the patient's insurer. *(April 24, 2003, Responses to Interrogatories, page 200)*

21. The Applicant will provide management and technical services to the facility. The Applicant will be responsible for booking and scheduling of patients at the Center. *(January 31, 2003, Completeness Responses, Exhibit L)*

22. The Practice performs cardiac interventions at Bridgeport Hospital and is accredited by Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories ("ICANL"). Most of its patients undergoing pharmacologic stress testing with SPECT currently will instead undergo stress testing with PET. Currently 3 to 4 patients daily undergo pharmacologic stress testing with SPECT. *(January 31, 2003, Completeness Responses, pages 133&134)*

23. ICANL is the principal independent agency responsible for setting standards for quality in nuclear cardiology and is the first and only program specifically created for the accreditation of nuclear cardiology imaging facilities. ICANL accreditation is linked to reimbursement for nuclear cardiology services provided by cardiologists in Connecticut. All major providers of nuclear cardiology services in Connecticut are ICANL certified. It is considered the standard of care for nuclear cardiology in the state. *(April 21, 2003, Applicant's Rebuttal to Request for Status by RSC, page 4)*

24. Cardiology Physicians, P.C. consists of 6 cardiologists, 5 Board Certified in Nuclear Cardiology, and provides most of the attending physicians to St. Vincent's Medical Center. The group has agreed to refer patients to the Center and has recently joined PRIMED, the largest multi-specialty physician group in Fairfield County, providing access to over 60 internal medicine and general practitioners for referrals. The group performs in excess of 2,000 MPI procedures annually. *(January 31, 2003, Completeness Response, page 134 and April 24, 2003, Responses to Completeness)*

25. The Applicant projects that the two cardiology practices that have signed up to provide the cardiac PET service to their patients will refer 160 patients per year per cardiologist based on the current number of SPECT scans performed by the two cardiology groups. *(January 31, 2003, Completeness Response, pages 134 and 138)*

26. Each physician group will be able to nominate a representative to the clinical advisory board of the Center, which advises the Center on issues of clinical significance such as clinical protocols, new procedures, or new clinical staffing needs. *(April 24, 2003, Responses to Interrogatories, page 199)*

27. The Applicant proposes to provide connectivity with referring physicians through a high speed Virtual Private Network solution. *(November 13, 2002, CON Application, page 17)*

28. The Applicant has contracted with an emergency room physician to provide test supervision and emergency medical services if needed for patients referred by physician groups. *(January 31, 2003, Completeness Response, page 139)*

29. The total equity interest held by all physician groups in total will not exceed 40%. The recent exemption of PET centers from the Stark self-referral laws will allow physician groups to share expensive PET scanners and deliver the highest quality of care. *(November 13, 2002, CON Application, page 50 and April 24, 2003, Responses to Interrogatories, page 199)*

30. In 1997, Medicare defined a new entity independent of a hospital or physician's office in which diagnostic tests are performed by licensed or certified non-physician personnel under appropriate physician supervision. The new entity is identified as an Independent Diagnostic Testing Facility ("IDTF"). *(November 13, 2002, CON Application, page 48)*

31. The Applicant is proposing to be federally designated as an IDTF and be accredited by the ICANL. *(November 13, 2002, CON Application, page 10)*

32. The ICANL recommends 300-500 annual nuclear cardiology procedures with PET or SPECT imaging. *(November 13, 2002, CON Application, page 51)*

33. The Center will initially meet the ICANL requirements based on the Practice's existing ICANL accreditation for nuclear cardiology. As long as the Medical Directors are the same, the Practice's accreditation will apply to the Center. After six months of operation, the Center can apply to receive its own independent accreditation. *(January 31, 2003, Completeness Response, pages 133 and 134 and April 24, 2003, Responses to Interrogatories)*

34. The Center's Quality Control Plan is the actual Quality Control Plan required by the ICANL. (*April 24, 2003, Responses to Interrogatories, page 199)*

35. The Applicant proposes to hire a full time executive director, part time technical and medical directors, full time certified technician (one initially, two when volume exceeds ten scans per day), nursing staff (one initially, two when patient load exceeds 8 patients per day) and a part time billing clerk. *(November 13, 2002, CON Application, page 16)*

36. The Applicant will become a Cardiac PET/CT reference site for Siemens Medical Systems in the area. *(April, 21, 2003, Letter from Siemens Medical Solutions USA, Inc.)*

37. The Applicant testified regarding the following:
    - 70% of physician offices are accredited by the ICANL.
    - Initially at least six physicians board certified in nuclear cardiology will be available for interpretation.
    - Currently the participating cardiology groups interpret in excess of 6,000 nuclear cardiology procedures annually.
    - Nationally over 8 million MPI procedures are performed annually. Nuclear cardiology utilization has increased 22.1% between 2001 and 2002.

- PET-MPI testing involves cardiac stress testing of patients at moderate to high risk of cardiovascular complications. A fixed site with cardiovascular trained clinical staff offers the best environment for safe and effective testing of cardiac patients.
- The Center has an aggressive sliding fee scale for uninsured patients offering the service for free to indigent patients.
- The Center's revenues will equal its expenses at less than 3 scans per day.

(April 25, 2003, Testimony of Johan Brag)

38. The Applicant's hours of operation for the proposed PET-CT imaging center are Monday through Friday from 8:00 a.m. to 6:00 p.m. The facility plans to extend coverage by an additional hour at night by year 2 and offer 24-hour emergency coverage within the third year of operation. *(March 11, 2003, CON Application, page 6)*

39. Fairfield County Mobile PET Collaborative ("FCMPC") received approval from OHCA to establish a mobile PET scanning service in Fairfield County, which is shared among Bridgeport Hospital, Danbury Hospital, Greenwich Hospital, Norwalk Hospital, St. Vincent's Medical Center and The Stamford Hospital. PET scan volume was projected to be 85% oncology, 10% neurology, and 5% cardiac. It began operations on October 1, 2002. FCMPC actually performed 97.2% oncology, 2.7% neurology, and 0.1% cardiac procedures from October 1, 2002 to March 31, 2003. *(April 24, 2003, Petition for Intervenor Status, Prefiiled Testimonies, and Docket Number 00-509)*

40. FCMPC has filed with OHCA a two-phased CON application seeking approval to use a second mobile PET scanner and upgrade to mobile PET-CT scanners as such technology becomes available in the Spring/Summer of 2003. *(April 24, 2003, Petition for Intervenor Status and Prefiiled Testimonies)*

41. The Applicant stated that there would be no impact on the mobile PET service approved for Fairfield County, which is dedicated to oncology and does not have the technical or logistic capability to perform PET-MPI or cardiac PET-CT procedures. No cardiac PET or cardiac CT facilities are currently operating in the state. *(November 13, 2002, CON Application, page 1)*

42. FCMPC testified at the Hearing as to the following:
    - "The proposed facility will negatively impact the volume of FCMPC as an existing provider of PET scanning services in Fairfield County and as a potential provider in the emerging area of MPI and other cardiac PET-CT services."
    - "The proposed facility will unnecessarily duplicate services that the FCMPC is planning to deliver."
    - "Incrementally increasing the number of pieces of equipment and days that this equipment can be made available to our service area populations, the Collaborative members will have access to the equipment necessary to perform all types of PET imaging, including performing cardiac studies, as these techniques gain approval by the FDA, CMS and other third party payors and become accepted as the standard of care."

- There will be no difference between what the Collaborative can offer in a mobile PET setting and the service that the Applicant's proposed facility can provide.
- FCMPC has not received any cardiac PET referrals.

(April 24, 2003, Petition for Intervenor Status and Prefiiled Testimonies)

43. Radiological Society of Connecticut, Inc. ("RSC") is a nonprofit organization of approximately 400 radiologists having the organizational purpose of serving patients and society by advancing the science of radiology, improving radiological service to the patient, studying the socioeconomic aspects of the practice of radiology and encouraging improved and continuing education for radiologists and allied professional fields. *(April 15, 2003, Petition for Status)*

44. RSC testified to the following:
    - "Radiologists have an interest in this application because our specialty is under siege. Regulators should be concerned that patients suffer when they do not have access to high-quality radiologists. The pernicious erosion of our specialty by self-referring specialists who have an economic incentive to control the flow of referrals makes it harder for hospitals to recruit excellent radiologists." *(April 28, 2003, Supplemental Pre-filed Testimony of Marc F. Glickstein, M.D., President of RSC, page 7)*
    - "Self-referral and other influences will move the volume for this procedure away from hospitals and out of the purview of radiologists." *(April 24, 2003, Pre-filed Testimony of Marc F. Glickstein, M.D., President of RSC, page 13)*
    - "Cardiologists are attempting to capture the cardiac PET imaging market to the exclusion of radiologists, thus depriving RSC members of their right to derive economic and intellectual benefit from the pursuit of their chosen livelihoods." *(April 24, 2003, Pre-filed Testimony of Marc F. Glickstein, M.D., President of RSC, page 15)*
    - "A dedicated cardiac PET imaging facility will prevent hospitals and radiologists from growing the modality and experiencing its economic benefits." *(April 24, 2003, Pre-filed Testimony of Marc F. Glickstein, M.D., President of RSC, page 15)*
    - "To allow the establishment of said facility to the exclusion of radiologists would be contrary to the interest of radiologists whose rights and interests RSC is bound to protect." *(April 24, 2003, Pre-filed Testimony of Marc F. Glickstein, M.D., President of RSC, page 15)*
    - "The Application will result in RSC member radiologists being denied the opportunity to pursue their livelihoods and obtain training and experience with respect to an emerging imaging modality." *(April 24, 2003, Pre-filed Testimony of Marc F. Glickstein, M.D., President of RSC, page 15)*

45. Section 19a-613 of the Connecticut General Statutes authorizes OHCA to collect patient-level outpatient data from health care facilities or institutions, as defined in Section 19a-630, C.G.S.

Financial Feasibility 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 Payers for Such Services

46. The proposal has a total capital cost of $2,861,274 as follows: *(November 13, 2002, CON Application, page 11)*

Table 4: Proposal's Projected Capital Cost

Description	Cost
Moveable Equipment	$70,000
Construction/Renovation	100,000
Total Capital Expenditure	**$170,000**
Fair Market Value of Fixed Equipment (Lease)	$2,691,274
Total Capital Cost	**$2,861,274**

47. The Applicant proposes to fund the project through lease financing of $2,691,000 and Applicant's equity through operations. *(November 13, 2002, CON Application, page 12)*

48. The Applicant proposes to acquire a Siemens Biograph PET-CT scanner as well as a radioisotope generator for MPI procedures. *(July 22, 2002 Letter of Intent, Project Description)*

49. The Applicant provided a cash flow statement and balance sheet for the proposed facility. *(March 11, 2003, Completeness Response, page 175)*

50. The Applicant provided an investor letter from David H, Smith, Managing Director of Tailwind V.C., LLC located in Greens Farm, Connecticut. The letter states "…Tailwind V.C., LLC, CONTRA V.C., LLC and Interim Advantage Fund, LLC as well as myself personally, will provide the necessary operating capital to HealthCenter Imaging estimated at $1.2 million. Combined these investment funds manage in excess of $40 million of assets. I am authorized to invest these funds as I see fit…" (*January 31, 2003, Completeness Response, page 172)*

51. The Applicant projects excess revenues with the Center of $3,439,521, $4,792,394, $6,092,568, and $7,364,414 for FYs 2004, 2005, 2006, and 2007. *(November 13, 2002, CON Application, page 14)*

52. If volume projections are achieved, the Applicant's rates are sufficient to cover the proposed capital cost and operating costs. *(November 13, 2002, CON Application, page 14)*

53. The Applicant's projected payer mix is approximately 45% total government and 55% commercial insurers. *(November 13, 2002, CON Application, page 13)*

54. Since March 14, 1995, Medicare has covered cardiac PET for myocardial perfusion imaging using Rubidium 82. (*National Coverage Determinations)*

55. Effective October 1, 2002, Medicare covers FDG PET for the determination of myocardial viability as a primary or initial diagnosis prior to revascularization or following an inconclusive SPECT. (*National Coverage Determinations)*

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.:

56. There is no State Health Plan in existence at this time. *(November 13, 2002, CON Application, page 3)*

57. The Applicant has adduced evidence that this proposal is consistent with the Applicant's long-range plan. *(November 13, 2002, CON Application, page 3)*

58. The Applicant's teaching and research responsibilities will not be affected by this proposal. *(November 13, 2002, CON Application, Question 7(a))*

59. There are no distinguishing characteristics of the patient/physician mix related to this proposal. *(November 13, 2002, CON Application, page 10)*

60. The Applicant did not provide evidence of activities to improve productivity and contain costs. *(November 13, 2002, CON Application, page 9)*

61. The Applicant has sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(November 13, 2002, CON Application, page 9 and Exhibit E)*

Rationale

HealthCenter Imaging, LLC ("Applicant") proposes to establish a dedicated cardiac PET-CT imaging center in Trumbull, Connecticut. Implementation of the proposal would establish the first PET-CT center dedicated to cardiac imaging in Connecticut. Integrated PET-CT scanners allow physicians to combine functional information from PET (measures of blood flow, cardiac wall motion, ejection fraction, and metabolism) with detailed anatomical information from CT (atherosclerotic plaque burden measurement and assessment of stenoses of the coronary arteries) for a comprehensive noninvasive diagnosis in a single study. The principal procedure to be offered at the proposed facility will be PET-MPI. PET MPI testing involves cardiac stress testing of patients at moderate to high risk of cardiovascular complications. Over 8 million MPI procedures are performed annually in the United States using nuclear cardiology technology (i.e., SPECT technology). PET has numerous advantages over the existing SPECT technology including higher sensitivity and resolution, improved specificity, and the ability to detect coronary artery disease at an earlier stage through quantification of blood flow reserve.

The Applicant based the need for the dedicated cardiac PET-CT imaging center ("Center") on projected growth in the demand for PET-CT and MPI services in the primary service area due to aging of the population and technology advances; scheduling backlogs at physician-office based cardiac imaging facilities; and referrals by service area physicians to the Center. The primary service area for the proposal is Fairfield County. The Applicant proposes to serve a population of 1 million residents who reside within a 20-mile traveling distance of the facility. The prevalence of chronic heart disease in Connecticut is 80 per 1,000 persons between 45 and 55 years of age, 200 per 1,000 for persons between 55 and 65, 273 per 1,000 persons between 65 and 74 and finally reaches 371 per 1,000 persons over the age of 75. The Applicant provided a target market opportunity analysis based on the specific incidence of various clinical indications where it has been demonstrated that PET provided clear evidence of superior patient management over SPECT. The results of this analysis indicate that 86,941 residents of the primary service area are potential candidates for PET-MPI procedures. The Applicant applied a 15% market penetration to its target market opportunity, demonstrating a potential of 3,800 patients within a 20-mile radius of the Center. The Applicant projects a total of 2,500, 3,250, 4,000 and 4,750 procedures in FYs 2004, 2005, 2006, and 2007. There is currently an average two-week backlog for SPECT imaging in Fairfield County. In Fairfield County, over 90% of all outpatient nuclear cardiology (SPECT) procedures are performed by cardiologists outside of the hospital. The Applicant stated that patients are currently either tested with less accurate techniques or referred to facilities in New York City.

The Applicant has contracted with two cardiology groups consisting of 16 cardiologists in Bridgeport, most of whom are Board-certified in Nuclear Cardiology. The Applicant anticipates that each of the cardiologists will have 160 PET-CT scan referrals to the Center on an annual basis. Cardiologists Specialists, P.C. ("Practice") will provide PET-

CT services to the Center. The Practice projects that 3 to 4 of its patients who currently undergo pharmacologic stress testing with SPECT on a daily basis will instead undergo stress testing with PET. The Practice will supervise at least 1,000 cardiac PET exams for patients booked by the Center. In addition, Cardiology Physicians, P.C. (now PRIMED) has agreed to refer patients to the Center. PRIMED is the largest multi-specialty physician group in Fairfield County, providing access to over 60 internal medicine and general practitioners for referrals. Cardiology Specialists, P.C. performs in excess of 2,000 MPI procedures annually.

The Practice will designate a Medical Director to assume medical accountabilities for all PET-CT services. The Medical Director will have overall clinical responsibility for the operations of the dedicated cardiac imaging center. The Practice will retain all decision-making authority regarding the selection of any of its patients for referral to the facility. The Applicant will provide management and technical services to the facility. A clinical staff specifically trained in cardiac imaging procedures will perform the studies. All decisions regarding testing will be made by the referring physician prior to referral to the Center. The Center will help verify eligibility with the patient's insurer. Physician supervision will be provided within the Center at all times to ensure patient safety. Most interpretations will be performed remotely by board-certified nuclear cardiologists typically operating from their respective offices. Onsite presence of the interpreting physician is not required. Since the Center and the Practice share a common building, physicians will most likely be available onsite for interpretations. The Applicant testified that tests will be supervised by board certified physicians and cardiologists. Initially, at least six physicians board certified in nuclear cardiology will be available for interpretation. Currently these physicians interpret in excess of 6,000 nuclear cardiology procedures annually. All physician groups will be able to nominate a representative to the clinical advisory board of the Center. The Applicant has contracted with an emergency room physician to provide test supervision and emergency medical services if needed for patients referred by physician groups. The Applicant will provide connectivity with referring physicians through a high speed Virtual Private Network solution.

The Applicant is proposing to be federally designated as an IDTF and be accredited by the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories ("ICANL"). The IDTF model allows multiple physician groups to refer patients to the facility, share in the interpretation of studies and provide a cost-effective, high quality service to cardiac patients as part of a comprehensive cardiovascular care program. The total equity interest held by all physician groups will not exceed 40%. ICANL is the principal independent agency responsible for setting standards for quality in nuclear cardiology and is the first and only program specifically created for the accreditation of nuclear cardiology imaging facilities. All major providers of nuclear cardiology services in Connecticut are ICANL certified. It is considered the standard of care for nuclear cardiology in the state. The Center's quality control plan is the actual plan of the ICANL. The ICANL recommends 300-500 annual nuclear cardiology procedures with PET or SPECT imaging. The recent exemption of PET centers from the Stark self-referral laws will allow physician groups to share expensive PET scanners and deliver the

highest quality of care. The Center will be a Cardiac PET-CT reference site for Siemens Medical Systems in the area. OHCA finds that the Applicant's proposal will improve both the quality and accessibility of PET-CT services for the noninvasive assessment of heart disease.

In addition, Section 19a-613 of the Connecticut General Statutes authorizes OHCA to collect patient-level outpatient data from health care facilities or institutions. The submission of quarterly utilization reports to OHCA by the Applicant will provide OHCA with the data necessary to monitor the quality and accessibility of care provided at the Center.

The Applicant stated that there would be no impact on Fairfield County Mobile PET Collaborative ("FCMPC"). FCMPC began operations of its mobile PET scanning service in Fairfield County on October 1, 2002. FCMPC projected scan volume to be 85% oncology, 10% neurology, and 5% cardiac. Since commencement of operations, FCMPC has performed 97.2% oncology, 2.7% neurology, and 0.1% cardiac procedures. The mobile PET service is dedicated to oncology and does not have the technical or logistic capability to perform PET-MPI or cardiac PET-CT procedures. FCMPC testified that it has not received any cardiac PET referrals. Also, FCMPC recently filed a two-phased CON application with OHCA to add a second PET scanner and upgrade to PET-CT. Although implementation of the FCMPC CON would provide FCMPC with the ability to perform cardiac studies, the major focus of the FCMPC mobile PET service is oncologic studies. Therefore, OHCA concludes that the Applicant's proposed Center will not specifically affect the FCMPC mobile PET service and will increase accessibility to PET-CT services for cardiac patients who reside in Fairfield County.

The Radiological Society of Connecticut, Inc. ("RSC"), which consists of radiologists and serves the interests of radiologists throughout the state, testified in opposition to this proposal. RSC stated that the proposed Center would allow cardiologists to provide services that should be performed by radiologists. However, the majority of noninvasive cardiac imaging is performed in physician offices. The services proposed to be offered at the Center are dedicated to cardiology studies, the Center will be manned by personnel that are highly trained in nuclear cardiology, and the Center will be supervised by board-certified nuclear cardiologists. It is worth noting again that in Fairfield County, over 90% of all outpatient nuclear cardiology (SPECT) procedures are performed by cardiologists outside of the hospital. It is evident that the procedures proposed to be offered by the Applicant are currently performed by cardiologists, not radiologists, in their offices. OHCA's jurisdiction does not include consideration the right of RSC members to derive economic and intellectual benefit from this service and pursue their chosen livelihoods. Therefore, OHCA concludes that the proposed Center will not specifically affect RSC members.

The proposal is financially feasible. The total capital cost of $2,861,274 is to be funded through lease financing of $2,691,000 and Applicant's equity through operations. The Applicant provided a balance sheet, cash flow statement, and an investor letter documenting sufficient funds available for the proposal. The Applicant projects excess

revenues with the Center of $3,439,521, $4,792,394, $6,092,568, and $7,364,414 for FYs 2004, 2005, 2006, and 2007. Since the Applicant testified that the Center is financially viable if it performs 3 scans per day and it is projecting to perform 2,500 scans in FY 2004, the financial projections appear to be reasonable and achievable. The Applicant's projected payer mix is approximately 45% total government and 55% commercial insurers The Applicant has provided an aggressive sliding fee scale for uninsured patients offering the service for free to indigent patients. Medicare covers cardiac PET for myocardial perfusion imaging and myocardial viability. OHCA concludes that the implementation of the Applicant's proposal is in the best interests of all payers and cardiac patients of PET-CT scanning services.

Based on the foregoing Findings and Rationale, the Certificate of Need Application of HealthCenter Imaging, LLC to establish a dedicated cardiac PET-CT imaging center to be located at 999 Silver Lane in Trumbull, Connecticut, at a total capital cost of $2,861,274, is hereby GRANTED.

Order

HealthCenter Imaging, LLC is hereby authorized to establish a dedicated cardiac PET-CT imaging center to be located at 999 Silver Lane in Trumbull, Connecticut, at a total capital cost of $2,861,274, subject to the following conditions:

1. This authorization shall expire May 20, 2005. 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 Applicant shall not exceed the approved capital expenditure of $2,861,274. In the event that the Applicant learns of potential cost increases or expects that the final project costs will exceed those approved, the Applicant shall file with OHCA a request for approval of the revised project budget.

3. The Applicant shall limit its procedures at the Center to the field of cardiology.

4. The Applicant shall submit written documentation of receipt of federal certification as an IDTF and accreditation by the ICANL by May 20, 2005.

5. The Applicant will provide OHCA with utilization reports on a quarterly basis. The data elements and the format and submission requirements are described in Attachment 1.

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:
May 20, 2003

Signed by:
Mary M. Heffernan
Commissioner

Revised Attachment I

HealthCenter Imaging LLC shall submit patient-specific data as listed and defined below for those patients that receive service, care, diagnosis or treatment at the dedicated cardiac PET-CT imaging center located in Trumbull, Connecticut. This information may be extracted from either the medical abstract or billing records or both and submitted to the Office of Health Care Access ("OHCA") in accordance with this Attachment.

I. The data are to be submitted in ASCII format on a computer disk or electronically.

II. Column headers to be used are listed below in parentheses after the name of each data element.

III. Data formats to be followed are listed for each data element.

IV. The disk or file should be clearly marked with the Applicant's/facility's name, file name, docket number and its contents.

V. Accompanying the data submission, the Applicant/facility must submit a full written description of the data submitted and its record layout.

VI. Initial data shall be submitted at the end of the first quarter in which the facility begins to provide the service it is licensed for. Subsequent data for a calendar quarter shall be filed before the end of the calendar quarter following the calendar quarter in which the encounter was recorded. This data set shall contain the data records for each individual encounter from that facility during the preceding calendar quarter. For example, the data set to be filed before June 30, 2004 shall contain the data records for each individual encounter at that facility from January 1, 2004 until March 31, 2004.

VII. All data collected by OHCA will be subject to the laws and regulations of the State of Connecticut and the Office of Health Care Access regarding its collection, use, and confidentiality.

Patient Data Elements

1. Medical Record Number (mrn) – unique patient identification number assigned to each patient for whom services are provided by a facility that distinguishes by itself the encounter of an individual patient from the encounter of all other patients for that facility. **Format: string (20, zero filled to left if fewer than 20 characters)**

2. Patient Control Number (patcont) – unique number assigned by the facility to each patient's individual encounter that distinguishes the medical and billing

records of the encounter. **Format: string (20, zero filled to left if fewer than 20 characters)**

3. Date of birth (dob) – the month, day, and year of birth of the patient whose encounter is being recorded. **Format: date (20, dd-mmm-yyyy hh:mm:ss)**

4. Sex (sex) – patient's sex, to be numerically coded as follows:
   a. Male = 1
   b. Female = 2
   c. Undetermined = 3

   Format: string (1)

5. If available, Race (race1, race2, race3, race4, race5, race6) – patient-identified designation(s) of one or more categories from the following list, and numerically coded as follows:
   a. White = 1
   b. Black/African American = 2
   c. American Indian/Alaska Native = 3
   d. Native Hawaiian/Other Pacific Island = 4
      (e.g., Native Hawaiian, Guamanian or Chamorro, Samoan, Other Pacific Islander.)
   e. Asian = 5
      (e.g., Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, other Asian)
   f. Some other race = 6

   Format: string (1)

6. If available, Ethnicity (pat_eth) –patient-identified cultural origin listed below, as from time to time amended, and numerically coded as follows:
   a. Hispanic/Latino = 1
      (i.e., Mexican, Puerto Rican, Cuban or other Hispanic or Latino)
   b. Non-Hispanic/Latino = 2

   Format: string (1)

7. Zip Code (patzip) - the zip code of the patient's primary residence. **Format: string (5)**

8. Date that Procedure was Scheduled (Booking Date) – means the month, day, and year on which the procedure or service was scheduled for a patient by the provider. **Format: date (20, dd-mmm-yyyy hh:mm:ss)**

9. Date of Encounter or Service (doe) – means the month, day, and year of the procedure or service for the encounter being recorded. **Format: date (20, dd-mmm-yyyy hh:mm:ss)**

10. Principal Diagnosis (dx1) – the ICD-9-CM code for the condition which is established after the study to be chiefly responsible for the encounter being recorded. **Format: String (5, do not include decimal place -- decimal place is implied)**

11. Secondary Diagnoses (dx2 through dx10) – the ICD-9-CM codes for the conditions, exclusive to the principal diagnosis, which exist at the time the patient was treated or which developed subsequently to the treatment and which affect the patient's treatment for the encounter being recorded. Diagnoses which are associated with an earlier encounter and which have no bearing on the current encounter shall not be recorded as secondary diagnoses. **Format: String (5, do not include decimal place -- decimal place is implied)**

12. E-code (ecode) – The ICD-9-CM codes for external cause of injury, poisoning or adverse effect. **Format: string (5, do not include decimal place -- decimal place is implied)**

13. Principle Procedure (px1) - the CPT-4/HCPCS code for the procedure most closely related to the principal diagnosis that is performed for the definitive treatment of the patient. **Format: string (5)**

14. Secondary Procedure (px2 through px10) – the CPT-4/HCPCS codes for other significant procedures. **Format – string (5)**

15. Modifier (mod1 through mod10) – means by which a physician indicates that a service or procedure performed has been altered by some specific circumstance but not changed in definition or code. **Format: string (2)**

16. Payment sources (Primary (ppayer), Secondary (spayer) and Tertiary (tpayer)) - the major payment sources that were expected at the time the dataset was completed, from the categories listed below:

a. Self pay	=	A
b. Worker's Compensation	=	B
c. Medicare	=	C
d. Medicaid	=	D
e. Other Federal Program	=	E
f. Commercial Insurance Company	=	F
g. Blue Cross	=	G
h. CHAMPUS	=	H
i. Other	=	I
j. Title V	=	Q
k. No Charge	=	R
l. HMO	=	S
m. PPO	=	T

Format: string (1)

17. Payer Identification (payer1, payer2, payer3) – the insured's group number that identifies the payer organization from which the facility expects, at the time of the encounter, some payment for the bill. Up to three payer organizations shall be reported in the order of their expected contributions to the payment of the facility's bill. **Format: string (5, zero filled to left if fewer than 5 characters)**

18. Encounter type (etype) – indicates the priority of the encounter.
    a. Emergent = 1
    b. Urgent = 2
    c. Elective = 3
    Format: string (1)

19. Referring Physician (rphysid) -- State license number of the physician that referred the patient to the service/treatment/procedure rendered. **Format: string (6)**

20. Operating Physician (physid) – State license number identifying the provider who performed the service/treatment/procedure. **Format: string (6)**

21. Charges (chrg_tot) – Total charges for this encounter. **Format: numeric (8)**

22. Disposition (pstat) – the circumstances of the patient's discharge, categories of which are defined below and from time to time amended:
    a. Discharged home = 1
    b. Referred for medical treatment = 2
    c. Transferred to another health care facility = 3
    d. Expired = 4
    e. Other = 5

    Format: string (1)