

Office of Health Care Access Certificate of Need Application

Final Decision

| Applicant: | Saint Francis Hospital and Medical Center |
|----------------------|--|
| Docket Number: | 07-31044-CON |
| Project Title: | Acquisition and Operation of a New Fixed-Based, 64-Slice, PET/CT Scanner in Place of a Three-Day per Week, Mobile-Based PET/CT Scanner |
| Statutory Reference: | Section 19a-639 of the Connecticut General Statutes |
| Filing Date: | January 4, 2008 |
| Decision Date: | March 24, 2008 |
| Default Date: | April 3, 2008 |
| Staff Assigned: | Jack A. Huber |

Project Description: Saint Francis Hospital and Medical Center proposes to acquire and operate a new fixed-based, 64-slice, positron emission tomography/computed tomography ("PET/CT") scanner in place of a three-day per week, mobile-based PET/CT scanner, at a total capital cost of \$5,006,941.

Nature of Proceedings: On January 4, 2008, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from Saint Francis Hospital and Medical Center ("Hospital") seeking authorization to acquire and operate a new fixed-based, 64-slice, positron emission tomography/computed tomography ("PET/CT") scanner in place of a three-day per week, mobile-based PET/CT scanner, at a total capital cost of \$5,006,941. The Hospital is a health care facility or institution as defined in Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A notice to the public concerning OHCA's receipt of the Hospital's Letter of Intent was published in the *Hartford Courant* on October 1, 2007. OHCA received no responses from the public concerning the Hospital's proposal. Pursuant to Section 19a-639, C.G.S., three individuals or an individual representing an entity with five or more people had until January 25, 2008, the twenty-first calendar day following the filing of the Hospital's CON Application, to request that OHCA hold a public hearing on the Hospital's proposal. OHCA received no hearing requests from the public.

OHCA's authority to review and approve, modify or deny this CON application is established by Section 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 Hospital'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. Saint Francis Hospital and Medical Center ("Hospital") is a tertiary acute care, hospital located at 114 Woodland Street, Hartford, Connecticut. (*January 4, 2008, CON Submission, pages 2 and 4*)
- 2. The Hospital operates a Level 2 Trauma Center, a Level III neonatology intensive care center, a large open heart surgery program and a regional cancer center as well as other health services. As an affiliate of the University of Connecticut School of Medicine, the Hospital trains a large number of interns and residents as well as other allied health professionals. (*January 4, 2008, CON Submission, pages 2, 4 and 15*)
- 3. The Hospital initiated a mobile-based positron emission tomography ("PET") service in 2002 after receiving Certificate of Need ("CON") authorization from the Office of Health Care Access ("OHCA") under Docket Number: 01-509. (*January 4, 2008, CON Submission, page 4*)
- 4. On January 27, 2004, OHCA authorized the Hospital to upgrade its mobile-based PET service to a three day a week mobile-based positron emission tomography/computed tomography¹ ("PET/CT") service in a CON approval under existing Docket Number: 01-509. (*January 4, 2008, CON Submission, page 4*)

¹ PET/CT is a non-invasive technique used for imaging a variety of physiologic processes in the body. It is utilized for detecting cancer and plays an important role in diagnosing neurodegenerative diseases and heart disease. A radioactive drug is administered to a patient that emits positrons which can be tracked by the PET/CT scanner. This technology can diagnose disease earlier and more accurately than with standard non-molecular imaging such as CT, MRI, ultrasound and nuclear gamma camera.

- 5. The Hospital proposes the following changes to its PET/CT service:
 - Acquire and operate a new fixed-based, Siemens Biograph 64-slice PET/CT scanner;
 - Relocate the PET/CT service from the Hospital's Health Enhancement Center at 95 Woodland Street, Hartford to the main Hospital building at 114 Woodland Street, Hartford;
 - Renovate existing space in the imaging department to accommodate the proposed fixed-based scanner; and
 - Discontinue the service arrangement with the mobile equipment vendor. (*January 4, 2008, CON Submission, pages 3 through 5*)
- 6. The Hospital indicates it serves a 23 town primary service area and a 29 town secondary service area. The Hospital's primary service area includes the following towns: West Hartford, Hartford, East Hartford, Bloomfield, Windsor, Windsor Locks, East Granby, Granby, Suffield, South Windsor, Simsbury, Canton, Avon, Farmington, East Windsor, Ellington, Somers, Stafford/Union, Enfield, Manchester/Bolton, Andover, Vernon, and Tolland. (*January 4, 2008, CON Submission, page 17 and Attachment 3, page 439*)
- 7. The Hospital indicates that the proposal will not change the patient population served by the existing PET/CT service. (*January 4, 2008, CON Submission, page 17*)
- 8. The Hospital examined and offered information with regard to the need for the proposal as follows:
 - The benefits of PET/CT imaging in the Hospital's treatment of cancer, cardiovascular and neurodegenerative cases;
 - Data published in the PET/CT literature; and
 - The Hospital's historical PET/CT utilization and demographic trends. (*January 4, 2008, CON Submission, page 5*)

PET/CT Imaging for Cancer Services

- 9. The Hospital indicates that the literature reflects the following:
 - According to the Association of American Cancer Institutes' publication entitled "AACI Member Legislative Visits – June 2003", 1.2 million Americans are diagnosed with cancer every year and that 560,000 Americans will die from cancer in 2003;
 - According to a National Cancer Institute estimate, the overall cancer survival rate is 62%; and
 - According to an American Cancer Society publication entitled "Cancer Fact and Figures 2007", for Connecticut in 2007 there were 19,780 new cancer cases and incidence rates for all cancer sites were 597.3 per 1,000 for males and 448.3 per 1,000 for females between the years 1999 through 2003. (*January 4, 2008, CON Submission, pages 5 and 6*)

- The Hospital has been operating the Saint Francis/Mount Sinai Regional Cancer Center ("Center") since 1993. A wide variety of cancers are treated at the Center including brain, pharynx, lung, colon, stomach, prostate, beast, leukemia, etc. (*January 4, 2008, CON Submission, page 6*)
- 11. The Center has been designated a Teaching Hospital Cancer Program by the Commission on Cancer of the American College of Surgeons. (*January 4, 2008, CON Submission, page 6*)
- 12. The Center provides medical, hematology immunology, radiation oncology, surgical oncology and a Comprehensive Breast Health Center. The Center is also home to the Connecticut CyberKnife Center where stereotactic image guided radiation therapy ("IGRT") procedures for treating cancer are performed. (*January 4*, 2008, CON Submission, page 6)
- 13. The Hospital indicates that more accurate treatment can be performed using PET/CT for planning as opposed to conventional CT or magnetic resonance imaging ("MRI"). (*January 4, 2008, CON Submission, page 6*)
- 14. Frequently, patients undergoing PET/CT scanning have complex medical problems, which require other imaging services such as MRI or ultrasound. The proposed relocation of the service will assist cancer patients and their physicians in allowing for better scheduling of examinations and coordination of services. (*January 4, 2008, CON Submission, page 6*)
- 15. The Hospital indicates that the proposed PET/CT scanner will accomplish the following with respect to cancer care:
 - For IGRT treatment planning, the CT system will render images with 0.4 millimeter resolution as well as current crystal and detector technology that offers high system sensitivity for accurate PET imaging on even the largest patient;
 - Respiratory gating for imaging lung and liver tumors near the diaphragm which move during respiration; and
 - Software and hardware for 3D and volume analysis of PET/CT data as well as the ability to take CT and MRI imaging data from other Hospital imaging units and fuse/process/analyze the data to aide in determining extent of tumor and plan IGRT treatment. This capability is critical in meeting the demands of the Hospital's radiation oncologists and their patients undergoing Cyberknife therapy.

(January 4, 2008, CON Submission, page 6)

16. The Hospital's actual oncology utilization statistics for FYs 2005 through 2007 are as follows:

| Description | FY 2005 | FY 2006 | FY 2007 |
|---------------------------------|---------|---------|---------|
| Chemotherapy & Other O/P Visits | 45,536 | 44,755 | 46,092 |
| Radiation Therapy* | 17,488 | 16,657 | 16,733 |
| CyberKnife Volume | 0 | 80 | 281 |
| | | | |

Table 1: Actual Oncology Utilization Statistics

Note: * Declining radiation therapy volume is attributable to some treatments requiring a longer period of time to treat, the increasing complexity of cases being treated and OHCA approved centers in Manchester and Enfield.

(January 4, 2008, CON Submission, page 7)

PET/CT Imaging for Cardiovascular Services

17. The Hospital indicates that the literature reflects the following:

- An American Heart Association statistical fact sheet states that in the United States cardiovascular disease is the leading cause of death: and
- According to a 2006 State of Connecticut publication entitled "The Burden of Cardiovascular Disease in Connecticut" cardiovascular disease accounted for 11,365 Connecticut resident deaths in 2002, or about 38% of all deaths for the period.

(January 4, 2008, CON Submission, page 11)

- 18. The Hospital operates the Hoffman Heart and Vascular Institute ("Heart Institute"). (*January 4, 2008, CON Submission, page 11*)
- 19. The Heart Institute provides a wide range of heart services including open heart surgery, cardiac catheterization, percutaneous transluminal angiography, stress testing, cardiac rehabilitation, echocardiography testing, electrophysiology, and electrocardiogram services. (*January 4, 2008, CON Submission, page 11*)
- 20. The Hospital's Heart Institute is accredited by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories, Commission on Accreditation of Allied Health Education Programs, American Association of Cardiovascular and Pulmonary Rehabilitation in addition to the Joint Commission on the Accreditation of Health Organizations. (*January 4, 2008, CON Submission, page 11*)
- 21. The Hospital has a large open heart surgery program and cardiovascular service that is supported by imaging services that include nuclear spectography, echocardiology, CT imaging and MR imaging. (*January 4, 2008, CON Submission, page 12*)

22. The fixed-based PET/CT will include software to allow the Hospital to perform PET/CT studies in certain cases for evaluating cardiac function viability in circumstances when patients may be unable to undergo a cardiac MRI for viability assessment. These cases arise when patients have had electronic devices implanted (i.e. pacemakers and defibrillators) or are too large to be accommodate in an MRI scanner. The Hospital anticipates about 1 to 2 cases per week for this of the new unit. (*January 4, 2008, CON Submission, page 12*)

PET/CT Imaging for Neurology Services

- 23. The Hospital indicates that it serves many neurology patients who require imaging services including PET/CT in the treatment of cerebrovascular disease, dementia, epilepsy and head trauma. (*January 4, 2008, CON Submission, pages 13 and 14*)
- 24. Neurological applications of PET/CT imaging include:
 - Detecting the early stages of Alzheimer's disease and other forms of dementia sooner than conventional CT and MRI by evaluating functional brain metabolism; and
 - Evaluating seizure foci, staging and mapping of brain tumors by producing brain images that will also allow for fusion and integration of these images with other modalities such as MRI to guide treatment planning and evaluation. (*January 4, 2008, CON Submission, page 14*)

Actual and Projected Imaging Utilization

25. The Hospital's actual PET/CT scan volumes for FYs 2004 through 2007 are as follows:

| Description | FY 2004 | FY 2005 | FY2006 | FY2007 | % Change FYs 2005 to 2007 |
|------------------------|---------|---------|--------|--------|------------------------------|
| Primary Service Area | 598 | 755 | 855 | 1006 | 33.2% |
| Secondary Service Area | 189 | 233 | 302 | 347 | 48.9% |
| Other Towns | 133 | 139 | 191 | 244 | 75.5% |
| Total | 920 | 1127 | 1348 | 1597 | 41.7% |

Table 2: Actual PET/CT Volume

(January 4, 2008, CON Submission, page 19 and Attachment 5, page 450)

26. The Hospital's projected PET/CT scan volumes by service for the first three years with the fixed-based scanner are as follows:

| Table 3: Projected PET/CT Volume | | | |
|----------------------------------|--------|--------|--------|
| Description | Year 1 | Year 2 | Year 3 |
| Oncology | 2,078 | 2,452 | 2,826 |
| Cardiology | 104 | 130 | 156 |
| Neurology | 126 | 142 | 158 |
| Total | 2,308 | 2,724 | 3,140 |

Note: The data presented by the Hospital could not be verified by OHCA. (*January 4, 2008, CON Submission, page 21*)

- 27. The Hospital based its PET/CT volume projections on the following factors:
 - Continued PET outpatient imaging growth;
 - Projected 3.5% service area population growth between 2005 and 2010;
 - Current case mix and expected cardiac case volume at the Hoffman Heart and Vascular Institute; and
 - The Hospital's participation in the National Oncology PET Registry, which is expected to stimulate more use of PET/CT that has been experienced to date. (*January 4, 2008, CON Submission, pages 15 and 16*)

28. The Hospital indicates the following future trends in PET/CT imaging:

- The PET/CT market will continue to experience rapid growth over the next five years;
- Reimbursed clinical applications, particularly in cancer, are expanding significantly;
- Many institutions are transforming from a one day a week mobile PET service to a fixed site operation; and
- All of the diseases in which PET/CT is most heavily used will increase in prevalence over the coming decade.
 (*January 4, 2008, CON Submission, pages 15 and 16*)
- 29. The Hospital indicates that due to the high demand for service the limited three days per week provided by the mobile service can no longer meet the Hospital's increasing demand. The capacity of the mobile-based PET/CT scanner is estimated to be 1,579 scans per year. The projected capacity of the new fixed-based PET/CT scanner is 3,795 scans per year. (*January 4, 2008, CON Submission, pages 21 and 22*)

30. The Hospital identified the following PET/CT providers in its service area:

| ServiceProviderMobile UnitBristol Hospital | | Hours/Days of Operation | Current Utilization | |
|--|-----------------------|----------------------------|------------------------|--|
| | | 2 days per week; | 1040 per year | |
| | | 7 am to 5 pm | | |
| Mobile Unit | New Britain General | 1 day per week; | 416 per year | |
| | | 7 am to 6 pm | | |
| Fixed Unit | Hartford Hospital | 5 days per week; | 2340 per year | |
| | | 7 am to 5 pm | | |
| Fixed Unit | Middlesex Hospital | 5 days per week; | 1040 per year | |
| | | 7 am to 5 pm | | |
| Mobile Unit | John Dempsey Hospital | 1 day per week; | 768 per year | |
| | | plus 1 Thurs. per month; | | |
| | | 7:30 am to 6:30 pm | | |
| Mobile Unit | MidState Medical | 1 day per week; | 520 per year | |
| | Center | 7 am to 6 pm | | |
| Mobile Unit | Manchester Memorial | 1 day per week | 312 per year | |

 Table 4: Current PET/CT Availability in the Hospital's Service Area

(January 4, 2008, CON Submission, page 22)

- 31. The Hospital does not believe the proposal will have any significant affect on other area providers of the same service. (*January 4, 2008, CON Submission, page 23*)
- 32. The current mobile PET/CT service operates on Mondays, Fridays and Saturdays. The current backlog for PET/CT examinations has been averaging two to three weeks. (*January 4, 2008, CON Submission, page 16*)
- 33. The Hospital estimates that 40% or 631 patients experience a waiting time up to three weeks from the time the imaging request is made until the exam is performed. (*January 4, 2008, CON Submission, page 16*)
- 34. The proposed hours of operation for the fixed-based PET/CT scanner will be Monday through Friday for eight hours each day. (*January 4, 2008, CON Submission,* page 19)
- 35. The Hospital will meet the ACR guidelines through clinical policies and procedures, medical staff credentialing, and quality assurance processes. (*January* 4, 2008, CON Submission, pages 25 through 27)

Financial Feasibility and Cost Effectiveness of the Proposal and its Impact on the Hospital's 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

- 36. The total capital expenditure of the project is \$5,006,941. The costs are itemized as follows:
 - \$2,620,800 for purchase of the PET/CT scanner;
 - \$1,908,158 for building work to accommodate the new scanner;
 - \$220,471 for architect/engineering fees and project contingency;
 - \$203,444 for purchased medical equipment; and
 - \$54,068 for purchased non-medical equipment. (*January 4, 2008, CON Submission, pages 33 and 34*)
- 37. The proposed service space will total 2,930 departmental gross square feet and will be located in a renovated portion of the Imaging Department. The scanning area will occupy a former film storage room, which has been freed for other use with the Hospital's implementation of its digital file storage system. (*January 4*, 2008, CON Submission, page 34)
- Renovation work is scheduled to begin in April 2008 and will be completed in September 2008. Scanning operations will likewise commence in September. (*January 4, 2008, CON Submission, page 35*)
- 39. The renovations will not negatively affect the delivery of health services within the Imaging Department or the Hospital. (*January 4, 2008, CON Submission, page 34 and 35*)
- 40. The project will be financed entirely through the Hospital's funded depreciation account. (*January 4, 2008, CON Submission, page 36*)
- 41. The Hospital projects incremental revenue from operations, total operating expense and losses/gains from operations associated with the CON proposal for FY 2009 through FY 2011 as follows:

| Table 5: Incremental Financial Projections for FYs 2009 - 2011 | | | |
|--|---------------|-------------|-------------|
| Description | FY 2009 | FY 2010 | FY 2011 |
| Incremental Revenue from Operations | \$1,562,767 | \$2,604,728 | \$3,738,218 |
| Incremental Total Operating Expense | (\$1,160,786) | (\$435,973) | (\$279,772) |
| Incremental (Loss)/Gain from Operations | \$2,723,553 | \$3,040,701 | \$4,017,990 |

(January 4, 2008, CON Submission, page 39 and Attachment 13, page 701)

42. There is no State Health Plan in existence at this time. (*January 4, 2008, CON Submission, page 3*)

- 43. The Hospital has adduced evidence that the proposal is consistent with its long-range plan. (*January 4, 2008, CON Submission, page 3*)
- 44. The Hospital has improved productivity and contained costs by undertaking energy conservation measures, employing group purchasing practices in its procurement of supplies and equipment and by participating in activities involving the application of new technologies. (*January 4, 2008, CON Submission, page* 28)
- 45. While the proposal will not result in any change to the Hospital's research responsibilities, the acquisition of the new scanner will assist in the training of interns and residents from the University of Connecticut, School of Medicine who rotate through the Hospital. (*January 4, 2008, CON Submission, pages 4, 15 and 32*)
- 46. The service's current and projected payer mix during the first three years of operating the proposed PET/CT scanner is as follows:

| Payer Mix | Current | Year 1 | Year 2 | Year 3 |
|----------------------|---------|--------|--------|--------|
| Medicare | 43.4% | 43.7% | 43.7% | 43.7% |
| Medical Assistance | 16.1% | 15.7% | 15.7% | 15.7% |
| TriCare or Champus | 0.2% | 0.2% | 0.2% | 0.2% |
| Total Government | 59.7% | 59.5% | 59.5% | 59.5% |
| Commercial Insurers | 37.2% | 37.4% | 37.4% | 37.5% |
| Self-pay | 2.4% | 2.4% | 2.4% | 2.4% |
| Workers Compensation | 0.7 | 0.7% | 07.% | 0.7% |
| Total Non-Government | 40.3% | 40.5% | 40.5% | 40.5% |
| Total Payer Mix | 100.0% | 100.0% | 100.0% | 100.0% |

Table 6: Current and Three-Year Projected Payer Mix

(January 4, 2008, CON Submission, page 38 and Attachment 13, page 713)

- 47. The Hospital indicates the proposal will not result in any change its patient/physician mix. (*January 4, 2008, CON Submission, page 32*)
- 48. The Hospital possesses sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. (*January 4*, 2008, CON Submission, page 27 and Attachment 8, pages 491 through 525)
- 49. The Hospitals rates are sufficient to cover the proposed capital expenditures and operating costs associated with the proposal. (*January 4, 2008, CON Submission, page 39 and Attachment 13, page 701*)

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.

Saint Francis Hospital and Medical Center ("Hospital") is a tertiary acute care, hospital, located at 114 Woodland Street, Hartford, Connecticut. The Hospital operates a Level 2 Trauma Center, a Level III neonatology intensive care center, a large open heart surgery program and a regional cancer center as well as other health services. As an affiliate of the University of Connecticut, School of Medicine, the Hospital trains a large number of interns and residents as well as other allied health professionals.

The Hospital proposes the following changes to its PET/CT service: acquire and operate a new fixed-based, Siemens Biograph 64-slice PET/CT scanner; relocate the PET/CT service from the Hospital's Health Enhancement Center at 95 Woodland Street, Hartford to the main Hospital building at 114 Woodland Street, Hartford; renovate existing space in the imaging department to accommodate the proposed fixed-based scanner; and discontinue the service contract with the current mobile equipment vendor. In support of the proposal the Hospital examined and offered information regarding the following: the Hospital's historical PET/CT utilization and service capacity parameters; and benefits to be derived through the use of PET/CT imaging for cancer, cardiovascular and neurologic imaging/staging.

With the three day per week operating schedule, the Hospital's PET/CT service performed approximately 1,600 scans in fiscal year ("FY") 2007, which reflects an average annual percentage increase of 20.9%, between FY 2005 and FY 2007. The new fixed-based PET/CT scanner is needed to meet the current and future requirements of the service. The projected capacity of the proposed scanner is 3,795 scans per year.

The PET/CT service supports Hospital programs in cancer, cardiovascular and neurologic care. Two of the Hospital's recognized center of excellence are its cancer and cardiovascular programs. Since 1993, the Hospital has been operating the Saint Francis/Mount Sinai Regional Cancer Center ("Center"). The Center provides medical, hematology immunology, radiation oncology and surgical oncology. It includes a Comprehensive Breast Health Center and is also home to the Connecticut CyberKnife Center, where stereotactic image guided radiation therapy procedures for treating cancers are performed. The Center has been designated a Teaching Hospital Cancer Program by the Commission on Cancer of the American College of Surgeons. The Hospital also operates the Hoffman Heart and Vascular Institute ("Heart Institute"). The Heart Institute is accredited by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories, Commission on Accreditation of Allied Health Education Programs, American Association of Cardiovascular and Pulmonary Rehabilitation in addition to the

Joint Commission on the Accreditation of Health Organizations. In conjunction with these programs, the proposed PET-CT scanner will produce superior images that will enhance the accuracy of tumor location and whose results will determine the responsiveness of tumors to cancer treatment regimens. The new PET-CT scanner images will assist in diagnosing cardiac as well as neurological conditions. A fixed unit available on a daily basis will enhance the Hospital's diagnostic and treatment planning services for cancer patients and allow greater flexibility in scheduling the various types of exams to be performed. Additionally, the fixed unit will benefit the training of interns and residents from the University of Connecticut, School of Medicine who rotate through the Hospital. Based on the foregoing reasons, OHCA concludes that the Hospital has demonstrated the need for the proposal and that the acquisition of the proposed fixed-based PET/CT scanner will improve both the quality and accessibility of PET-CT scans for the Hospital's patients.

The proposal's total capital cost of \$5,006,941 will be financed entirely through funded depreciation. The Hospital projects incremental gains from operations with the proposal of \$2,723,553, \$3,040,701, and \$4,017,990 in fiscal years 2009, 2010, and 2011 respectively. The Hospital's financial projections, and volumes upon which they are based, appear to be reasonable and achievable. Therefore, OHCA concludes the CON proposal is financially feasible and will improve access to quality PET/CT scanning services.

Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Saint Francis Hospital and Medical Center ("Hospital") to acquire and operate a new fixed-based, 64-slice, positron emission tomography/computed tomography ("PET/CT") scanner in place of a three-day per week, mobile-based, PET/CT scanner, at a total capital cost of \$5,006,941, is hereby GRANTED.

- 1. This authorization shall expire on October 1, 2009. Should the Hospital's fixed-based PET/CT scanner not be acquired and operational by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.
- 2. The Hospital shall not exceed the approved capital expenditure of \$5,006,941. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall notify OHCA immediately.
- 3. The Hospital shall terminate the contract for the mobile-based PET/CT scanner after the fixed-based PET/CT scanner has commenced operation. Furthermore, the Hospital shall provide evidence to OHCA of the termination of the contract for the mobile-based PET/CT scanner by no later than two months after the fixed-based PET/CT scanner has commenced operation.
- 4. The Hospital shall notify OHCA in writing of the following by no later than one month after the new scanner becomes operational:
 - a. The name of the fixed-based PET/CT scanner manufacturer; and
 - b. The model name and description of the fixed-based scanner.
- 5. The Hospital shall file with OHCA utilization statistics for the fixed-based PET-CT scanner 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 fixed-based, PET/CT scanner commenced operation. The quarterly reports shall include the following information:
 - a. Total number of scans scheduled for the fixed-based PET-CT scanner;
 - b. Total number of scans performed by the fixed-based PET-CT scanner;
 - c. Average patient waiting time from the scheduling of the scan to the performance of the scan;
 - d. Number of scans by patient zip code;
 - e. Hours and days of operation for each week and in total; and
 - f. Number of scans by Medicare diagnostic code.

6. Should the Hospital propose any change in the array of health care services offered and/or any change in its complement of existing major medical or imaging equipment, the Hospital shall file with OHCA appropriate documentation regarding its change, including either a Certificate of Need Determination Request or a Certificate of Need Letter of Intent.

Should the Hospital fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional actions as authorized by law.

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 Commissioner Vogel on March 24, 2008

Date

Cristine A. Vogel Commissioner

CAV: jah