

Office Of Health Care Access Certificate of Need Application

Final Decision

| Applicant: | Saint Francis Hospital and Medical Center |
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| Docket Number: | 06-30778-CON |
| Project Title: | Acquisition and Operation of a 128-Slice, Dual Source Computed Tomography Scanner |
| Statutory Reference: | Section 19a-639 of the Connecticut General Statutes |
| Filing Date: | October 13, 2006 |
| Decision Date: | November 21, 2006 |
| Default Date: | January 11, 2007 |
| Staff Assigned: | Jack A. Huber |

Project Description: Saint Francis Hospital and Medical Center proposes to acquire and operate a 128-slice, dual source computed tomography scanner, at a total capital cost of \$2,566,051.

Nature of Proceedings: On October 13, 2006, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from Saint Francis Hospital and Medical Center ("Hospital") seeking authorization to acquire a 128-slice, dual source computed tomography scanner, at a total capital cost of \$2,566,051. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Pursuant to Section 19a-639, 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 July 1, 2006. Pursuant to Public Act 05-75, three individuals or an individual representing an entity with five or more people had until November 3, 2006, 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 proposal is established by Section 19a-639, C.G.S. The provision 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, general acute care hospital located at 114 Woodland Street, Hartford, Connecticut. (*September 5, 2006, Initial CON submission, Attachment 11, page 546*)
- 2. The Hospital is proposing to acquire and operate an advanced CT system that will complement the Hospital's cardiac and neurosciences centers of excellence, providing improved diagnostic information for coronary artery disease, stroke, neuro-oncology, and oncology, trauma, orthopedics, neurology and pulmonary medicine. (*September 5, 2006, Initial CON submission, page 3*)
- 3. The Hospital currently operates three (3) CT scanners on its main campus. Two scanners are housed on the second floor Radiology Department, while the remaining unit is located on the first floor adjacent to the Emergency Department ("ED"), ED X-Ray and MRI suites. (*September 5, 2006, Initial CON submission, page 3*)
- 4. The Hospital's proposal will accomplish the following: (*September 5, 2006, Initial CON submission, page 3*)
 - Replace the Radiology Department's ten (10) year old Siemens Somatom Plus 40, single-slice CT scanner;
 - Acquire and operate a new Siemens Definition with dual source (two x-ray tubes and two detectors) 64-slice x 2, providing 128-slice CT capability; and
 - Renovate existing space within its Radiology Department to accommodate the proposed scanner.
- 5. The CT scanners unaffected by the proposal are as follows: (*October 13, 2006, Completeness Response, page 2*)
 - A five (5) year old, two-slice, Siemens Somatom Volume Access CT scanner. The unit was installed in 2001; and
 - A one and a half (1.5) year old, 16-slice, Siemens Somatom Sensation CT scanner. The refurbished unit was installed in 2006.

- 6. The single–slice CT scanner designated for replacement was purchased in 1996 for \$318,950, which was at the time below the Office of Health Care Access's Certificate of Need capital cost threshold for diagnostic imaging equipment. (*June 26, 2006, Letter of Intent submission, page 8*)
- 7. The Hospital provided the following information regarding the single-slice scanner designated for replacement: (*September 5, 2006, Initial CON submission, page 4*)
 - The unit is technically obsolete and no longer meets the Hospital's clinical needs;
 - The unit requires costly maintenance due to frequent breakdowns; and
 - The scanner is fully depreciated and has exceeded its useful life.
- 8. The Hospital indicates that acquiring a 128-slice CT scanner will allow for: (*September* 5, 2006, *Initial CON submission, page 4*)
 - Increased exam throughput in that the unit utilizes a two source/detector system that rotates simultaneously capturing image data in half the time required by conventional CT technology; and
 - The unit will deliver a wide range of clinical applications due to the system's advanced hardware and software components. Such a CT system will be able to support the tertiary clinical services provided by the Hospital.
- 9. The Hospital indicates that its primary service area encompasses a twenty-three (23) town area in North Central Connecticut. The primary service area towns include: 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. Additionally, the Hospital indicates that its secondary service area consists of a 29 town area that is contiguous to its primary service area towns. (September 5, 2006, Initial CON submission, page 12 and Attachment 2, page 235)
- 10. The population to be served by the proposed replacement CT scanner is contained with the Hospital's existing service area towns. (*September 5, 2006, Initial CON submission, p. 12*)
- 11. The Hospital treats over 32,000 inpatients, provides over 60,000 Emergency department visits and delivers over 82,000 outpatient visits through its many clinic programs. The Hospital operates a Level 2 trauma center, Level III neonatology program and an open heart surgery program and serves as a regional cancer center. (*September 5, 2006, Initial CON submission, page 3*)
- 12. The actual volume for the entire CT service for fiscal years ("FYs") 2003 through 2006 is as follows: (*October 13, 2006, Completeness Response, page 2*)

| Table 1. Hospital's Total Actual CT Service Volumes | | | | | |
|---|---------|---------|---------|-----------|--|
| Description | FY 2003 | FY 2004 | FY 2005 | FY 2006** | |
| Actual # CT Scans | 22,150 | 23,265 | 25,120 | 28,439 | |
| Incremental Volume Change Between FYs | | 1,115 | 1,855 | 3,319 | |
| % Volume Increase Between FYs | | 5.0% | 8.0% | 13.2% | |

Table 1: Hospital's Total Actual CT Service Volumes*

Note: *Actual volumes were verified to Hospital's FYs 2003 through 2005 Annual Reporting, Schedule 500. **Annualized estimate based on nine months of actual FY 2006 service volume data. 13. The actual volume for the Hospital's single-slice CT scanner designated for replacement is as follows: (*October 13, 2006, Completeness Response, page 2*)

| Table 2: Designated Scanner's Actual CT Service Volumes | |
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|---------------------------------------|---------|----------|----------|
| Description | FY 2004 | FY 2005 | FY 2006* |
| Actual # CT Scans | 6,455 | 6,914 | 7,397 |
| Incremental Volume Change Between FYs | | 459 | 483 |
| % Volume Increase Between FYs | | 7.1% | 7.0% |
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*Note: Annualized estimate based on nine months of actual FY 2006 service volume data.

14. The projected volumes for the entire CT service for FYs 2007 through 2009 with the proposed scanner is as follows: (*October 13, 2006, Completeness Response, page 14*)

Table 3: Hospital's Projected CT Service Volumes*

| Description | FY 2007 | FY 2008 | FY 2009 |
|---------------------------------------|---------|---------|---------|
| Projected # CT Scans | 32,085 | 36,209 | 40,876 |
| Incremental Volume Change Between FYs | 3,646 | 4,124 | 4,667 |
| % Volume Increase Between FYs* | 12.8%** | 12.9% | 12.9% |

Note: *Volume increases were estimated using the rate of growth experienced by the Hospital for CT services between FYs 2005 and 2006 of 11% for inpatient CT and 15% for outpatient CT. **Volume percentage increase for FY 2007 was calculated using FY 2006 projected/actual volume results.

15. The projected volumes for the proposed 128-slice CT scanner is as follows: (October 13, 2006, Completeness Response, page 3 and Attachment 2, page 19)

Table 4: Replacement Scanner's Projected CT Service Volumes*

| Description | FY 2007 | FY 2008 | FY 2009 |
|---------------------------------------|---------|---------|---------|
| Projected # CT Scans | 10,695 | 12,070 | 13,625 |
| Incremental Volume Change Between FYs | 1215 | 1,375 | 1,555 |
| % Volume Increase Between FYs* | 12.8%** | 12.9% | 12.8% |

Note: *Volume increases were estimated using the rate of growth experienced by the Hospital for CT services between FYs 2005 and 2006 of 11% for inpatient CT and 15% for outpatient CT.

** Volume percentage increase for FY 2007 was calculated using FY 2006 projected/actual volume results.

- Greater image clarity and resolution utilizing a unit possessing the most current CT scanning technology on the market;
- Faster exams that improve patient comfort and the overall patient experience, especially when imaging the elderly, obese individuals, trauma patients and those individuals with cardiac and pulmonary disease;
- Automatic controls that reduce the amount of radiation received by a patient of any age, while allowing for the appropriate radiation dosage to produce quality images;
- Less contrast material being required for an exam, which is safer for the patient;
- Improved imaging of vascular structures including the heart, coronary arteries, and other anatomy not currently possible on the existing single-slice CT scanner; and
- The scanner will be fully digitalized and the patient image/examination data will be fully integrated in the Hospital's picture achieving communications system.

^{16.} The proposed 128-slice CT scanner will feature the following enhancements: (September 5, 2006, Initial CON submission, pages 4 through 11)

- 17. The proposed 128-slice CT scanner possesses the ability to provide CT angiography¹ and CT cerebral perfusion imaging² services. (*September 5, 2006, Initial CON submission, pages 15 through 17*)
- 18. The Hospital indicates that the use of coronary CTA to diagnose a patient with coronary heart disease can decrease unnecessary admissions to the Hospital and decrease the length of stay for those patients admitted to the Hospital. The proposed scanner will also allow the Hospital to better triage patients in the Emergency Department as well as reduce the number of unnecessary angiography studies. *(September 5, 2006, Initial CON submission, page 17)*
- 19. The Hospital indicates the use of magnetic resonance imaging ("MRI") is the current standard for early stroke detection. The use of the proposed scanner will improve the triage of stroke patients to proper therapy as quality diagnostic images can be rendered in less time when utilizing the latest generation of CT scanner. CT imaging also does not limit individuals from receiving a diagnostic scan that may have implanted electronic devices and/or that may be claustrophobic, as is sometimes the case with magnetic resonance imaging. *(September 5, 2006, Initial CON submission, pages 17 and 18)*
- 20. The existing and proposed hours of operation for the Hospital's CT service are twentyfour (24) hours per day, seven (7) days a week. (*September 5, 2006, Initial CON submission, page 12*)
- 21. The Office of Device Evaluation of the Federal Department of Health and Human Services' Food and Drug Administration has provided Section 510(k) clearance to Siemens Medical Systems, USA, Inc. to market the Somatom Definition CT scanner. (October 13, 2006, Completeness Response, page 3 and Attachment 2, page 19)
- 22. Hospital's imaging services are accredited by the American College of Radiology ("ACR"). The Hospital will seek to maintain its accreditations for its CT imaging services from the ARC. (*September 5, 2006, Initial CON submission, page 19*)
- 23. All physicians interpreting CT studies will be board-certified radiologists. The coronary portion of an examination will be interpreted by either a board-certified radiologist or a board-certified cardiologist who meet the minimum ACR requirements for interpreting the coronary component of a coronary CTA examination or the minimum American College of Cardiology ("ACC") COATS Level 2 competency requirements for interpreting the coronary component of a coronary CTA examination, respectively. (*September 5, 2006, Initial CON submission, pages 19 and 20*)

¹ CT angiography or coronary "CTA" provides images of the blood vessels that can determine how the blood is flowing in arteries and veins throughout the body. The procedure can accurately assess the degree of coronary stenosis and composition of atherosclerotic plaques which result in the acute coronary syndrome. It is a procedure that is less invasive than traditional diagnostic angiograms. Areas of the body that are generally studied in this way include the brain, heart, lung, kidneys, liver and extremities.

² CT cerebral perfusion imaging utilizes 3-dimensional capabilities of the 128-slice system to evaluate intracranial vessels that allow for the early detection of a patient experiencing a stroke.

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

- 24. The total capital expenditure of the proposal is \$2,566,051. The project expenditures are itemized as follows: \$1,981,701 for the purchase of the CT scanner; \$350,000 for building work to accommodate the new scanner and \$234,350 for non-medical equipment acquisition. (*September 5, 2006, Initial CON submission, page 27*)
- 25. The proposed CT scanner will be installed within the area that currently housing the single-slice CT scanner. The proposal requires expansion of an exam room, control room and equipment room to accommodate the new CT scanner. Cooling, power and shielding requirements will also be updated. (*September 5, 2006, Initial CON submission, page 28*)
- 26. Patient care services will not be affected by the project as the renovation work will be accomplished in an existing imaging room. (September 5, 2006, Initial CON submission, page 29)
- 27. The Hospital anticipates that the two remaining CT scanners will be able to share the CT services workload until the proposed CT scanner is installed. (*September 5, 2006, Initial CON submission, page 29*)
- 28. The entire project will be financed through Hospital operating funds. (September 5, 2006, Initial CON submission, page 29)
- 29. The proposed scanner is scheduled to commence operation in July 2007. (September 5, 2006, Initial CON submission, page 29)
- 30. The Hospital projects incremental revenue from operations, total operating expense and gains from operations associated with the CON proposal as follows: (October 13, 2006, Completeness Response, page 3 and At6tachment 3, page 21)

| Table 5: Incremental Financial Projections | | | | | |
|--|-----------|-------------|-------------|--|--|
| Description | FY 2007 | FY 2008 | FY 2009 | | |
| Incremental Revenue from Operations | \$519,701 | \$1,118,003 | \$1,805,860 | | |
| Incremental Total Operating Expense | \$300,512 | \$667,423 | \$923,755 | | |
| Incremental Gain from Operations | \$219,189 | \$450,580 | \$882,105 | | |

- 24. There is no State Health Plan in existence at this time. (September 5, 2006, Initial CON submission, page 3)
- 25. The Hospital has adduced evidence that the proposal is consistent with its long-range plan. (*September 5, 2006, Initial CON submission, page 3*)

- 26. The Hospital has improved productivity and contained costs by undertaking energy conservation measures regarding its facility, employing group purchasing practices in its procurement of supplies and equipment and participating in activities involving the application of new technologies. (*September 5, 2006, Initial CON submission, page 22*)
- 27. As an affiliate of the University of Connecticut, School of Medicine, the Hospital trains a large number of interns and residents as well as allied health professionals. (*September 5, 2006, Initial CON submission, page 3*)
- 28. The proposal will not result in any changes to the Hospital's teaching and research responsibilities. (*September 5, 2006, Initial CON submission, page 26*)
- 29. The Hospital's current and projected payer mix during the first three years of operating the proposed CT scanner is as follows: (*September 5, 2006, Initial CON submission, Attachment 12, page 555*)

| Table 6. Current and Three-Year Projected Payer Mix with the Proposal | | | | | |
|---|---------|---------|---------|---------|--|
| Payer Mix | Current | Year 1 | Year 2 | Year 3 | |
| Medicare | 44.2% | 43.6% | 43.6% | 43.6% | |
| Medicaid | 15.4% | 15.5% | 15.5% | 15.5% | |
| TriCare (CHAMPUS) | 0.2% | 0.2% | 0.2% | 0.2% | |
| Total Government | 59.7% | 59.3% | 59.3% | 59.3% | |
| Commercial Insurers | 37.5% | 37.8% | 37.8% | 37.9% | |
| Self-pay | 2.1% | 2.2% | 2.2% | 2.2% | |
| Workers Compensation | 0.7% | 0.7% | 0.7% | 0.7% | |
| Total Non-Govt. | 40.3% | 40.7% | 40.7% | 40.7% | |
| Total Payer Mix | 100.00% | 100.00% | 100.00% | 100.00% | |
| | | | | | |

Table 6: Current and Three-Year Projected Payer Mix with the Proposal

- 30. The proposal will not result in any change to the Hospital's patient/physician mix. *(September 5, 2006, Initial CON submission, page 26)*
- 31. The Hospital possesses sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. (*September 5, 2006, Initial CON submission, page 20 and Attachment 7, pages 547 through 564*)
- 32. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs associated with the proposal. (*September 5, 2006, Initial CON submission, page 31 and Attachment 12, pages 547 through 564*)

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, general acute care hospital located at 114 Woodland Street, Hartford, Connecticut. The Hospital is proposing to acquire and operate a 128-slice, dual source computed tomography ("CT") scanner, renovate existing space to accommodate the new scanner and remove an existing ten-year old, single-slice Somatom Plus 40 CT scanner from service. The proposed CT system is intended to complement the Hospital's cardiac and neurosciences centers of excellence, providing improved diagnostic information for coronary artery disease, stroke, neuro-oncology, oncology, trauma, orthopedics, neurology and pulmonary medicine. The Hospital also operates two other on-campus CT scanners as follows: a five year old, twoslice, Siemens Somatom Volume Access CT scanner and a one and a half year old, 16slice, Siemens Somatom Sensation CT scanner.

The need for the project is based on the technological obsolescence of the current 10-year old CT scanner and advancements that have been made in the field of CT technology. In addition, the current 10-year old CT scanner requires costly maintenance due to frequent breakdowns, has exceeded its useful life and has become fully depreciated. The Hospital intends to acquire and operate a new Siemens Definition with Dual Source (two x-ray tubes and two detectors) 64-slice x 2, CT scanner, providing 128-slice CT capability. The proposed scanner will provide improved quality imaging and reduced dosages of radiation and contrast media per examination. Acquisition of the 128-slice CT scanner will allow the Hospital to increased CT exam throughput in that the dual detector system will capture image data in half the time required by conventional CT technology.

The proposed CT scanner will also support the tertiary clinical services provided by the Hospital. Hardware and software advancements in CT scanning technology will allow the Hospital to deliver a wide range of clinical applications. CT angiography ("coronary CTA") and CT cerebral infusion imaging are two examples of advanced procedures that the Hospital will be able to perform with the proposed CT scanner. The benefit to Hospital patients receiving coronary CTA to diagnose coronary heart disease will be significant. The use of this procedure has the potential to decrease unnecessary inpatient admissions and decrease the length of stay for those patients presenting with symptoms in the emergency department as well as reducing the number of unnecessary angiography studies. Cerebral perfusion CT studies will provide essential diagnostic information for stroke treatment. The use of the proposed CT scanner should improve the triaging of stroke patients to proper therapy as quality diagnostic images can be rendered in less time.

The Hospital's actual volume for its three (3) CT scanner service is 22,150, 23,265, 25,120 and 28,439 scans for fiscal years ("FYs") 2003 through 2006, respectively. The actual volume for the Hospital's single-slice CT scanner designated for replacement is 6,455, 6,914 and 7,397 for FYs 2004 through 2006, respectively. Based on the foregoing reasons, OHCA finds that the Applicant has provided sufficient evidence to substantiate the need for the proposed CT scanner acquisition and that the proposal will improve the quality and accessibility of CT services in the greater Hartford region.

The total capital cost for the CON proposal is \$2,566,051. The project will be financed entirely through an equity contribution from the Hospital. In relationship to the proposal the Hospital projects incremental gains from operations of \$219,189 and \$450,580 in FYs 2007 and 2008, respectively. Although OHCA can not draw any conclusions, the Hospital's volume and financial projections upon which they are based appear to be reasonable.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Saint Francis Hospital and Medical Center to acquire and operate a 128-slice, dual source computed tomography scanner at a total capital expenditure of \$2,566,051, is hereby granted subject to conditions.

Order

Saint Francis Hospital and Medical Center ("Hospital") is hereby authorized to acquire and operate a 128-slice, dual source computed tomography scanner ("CT") scanner, at a total capital expenditure of \$2,566,051, subject to the following conditions:

- 1. This authorization shall expire on July 1, 2008. Should the Hospital's CT imaging project not be completed 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 total capital cost of \$2,566,051. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised CON project budget.
- 3. This authorization requires the removal of the Hospital's existing Siemens Somatom CT scanner for certain disposition, such as sale or salvage, outside of and unrelated to the Hospital's various service provider locations. Furthermore, the Hospital will provide evidence to OHCA of the disposition of the existing Siemens Somatom CT scanner to be replaced by no later than six months after the replacement Siemens Definition 128-slice, dual source CT scanner has become operational.
- 4. The Applicant shall notify OHCA in writing of the following information by no later than one month after the new 128-slice, dual source scanner becomes operational:
 - a) The name of the CT scanner manufacturer;
 - b) The model name and description of the CT scanning unit; and
 - c) The initial date of the operation of the CT scanner.

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

November 21, 2006

Signed by Cristine A. Vogel Commissioner

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