



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Yale-New Haven Hospital

Docket Number: 08-31127-WVR

Project Title: Request to Waive CON Requirements for the Replacement of the Existing Pediatric Cardiac Catheterization Laboratory

Statutory Reference: Section 19a-639c of the Connecticut General Statutes

Filing Date: June 13, 2008

Decision Date: June 20, 2008

Staff: Diane Duran

Project Description: Yale-New Haven Hospital requests a waiver of Certificate of Need (“CON”) requirements for replacement equipment for the purpose of replacing its existing pediatric cardiac catheterization laboratory system equipment in New Haven, at a total capital cost of \$5,092,358.

Nature of Proceedings: On June 13, 2008, the Office of Health Care Access (“OHCA”) received the completed waiver of Certificate of Need (“CON”) request for replacement equipment from Yale-New Haven Hospital (“Hospital”). The Hospital proposes to replace its pediatric cardiac catheterization laboratory system equipment, at a total capital cost of \$5,092,358.

OHCA’s authority to review and approve, modify or deny the requested waiver of CON requirements for replacement equipment is established by Section 19a-639c of the 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

1. Yale-New Haven Hospital is an acute care hospital located at 20 York Street in New Haven, Connecticut. *(June 13, 2008, CON Waiver Form 2040, page 1)*
2. On June 30, 1995, in an Agreed Settlement under the Docket Number 95-508, Yale-New Haven Hospital (“Hospital”), received Certificate of Need (“CON”) authorization from the Commission on Hospitals and Health Care (“CHHC”), predecessor to the Office of Health Care Access (“OHCA”) for a replacement of the Hospital’s Pediatric Catheterization Laboratory located at the Hospital on 20 York Street in New Haven, at a total capital expenditure of \$2,636,167. *(June 13, 2008, CON Waiver Form 2040, page 2 and June 30, 1995, Agreed Settlement, Docket Number: 95-508, pages 10 and 12)*
3. Additionally, on June 30, 1995, in the Agreed Settlement under the Docket Number 95-508, the Hospital was granted approval of its existing Catheterization Laboratory, which was purchased approximately seven years ago, and did not have any salvage value associated with the Hospital’s current equipment and therefore, replacement and removal of the equipment occurred at the Hospital on 20 York Street in New Haven. *(June 13, 2008, CON Waiver Form 2040, page 2, June 30, 1995, Agreed Settlement, Docket Number: 95-508, page 10)*
4. On January 22, 1997, in the Modification under the Docket Number 96-562Ra, the Hospital was authorized by OHCA, to extend the date by which the Hospital must report data and statistical results for its pediatric and adult diagnostic cardiac catheterization services and modified Stipulation #11 of the Agreed Settlement under Docket Number 95-508. *(June 13, 2008, CON Waiver Form 2040, page 2, and January 22, 1997, Modification, Docket Number: 96-562Ra, page 2)*
5. The Hospital houses one pediatric cardiac catheterization laboratory system located at 20 York Street in New Haven. *(June 13, 2008, CON Waiver Form 2040, pages 2 and 5)*
6. The Hospital is requesting a waiver of CON requirements in order to replace its existing Phillips, BH 300, Biplane imaging system, pediatric catheterization laboratory system authorized by OHCA. *(June 13, 2008, CON Waiver Form 2040, page 3)*
7. Pursuant to Section 19a-639c of the Connecticut General Statutes (“C.G.S”), a proposal may be eligible for a waiver of replacement equipment from the CON process when a provider has previously received Certificate of Need authorization from OHCA for the equipment to be replaced and when the cost or value of the replacement equipment will not exceed \$3 million. *(Section 19a-639c, C.G.S.)*
8. The Hospital plans to acquire and operate a GE Innova, 2121IQ, Biplane x-ray system, pediatric catheterization laboratory system, as its replacement equipment located at 20 York Street in New Haven. *(June 13, 2008, CON Waiver Form 2040, page 3)*

9. The Hospital indicates that its current operating hours for the pediatric cardiac catheterization laboratory system service are Monday through Friday, 7:30 a.m. – 8 p.m., and is on an as needed basis/covered by on-call staff Monday through Friday from 8 p.m. – 7:30 a.m. and all day Saturday and Sunday. *(June 13, 2008, CON Waiver Form 2040, page 37)*
10. The Hospital states that the existing pediatric cardiac catheterization laboratory system equipment needs to be replaced for the following reasons: *(June 13, 2008, CON Waiver Form 2040, pages 5 and 6)*
- The equipment is over 11 years old and is at the end of its useful life;
 - Increasing breakdowns, repairs and maintenances; and
 - As catheter based therapies have become increasingly complex, requiring longer and potentially more frequent procedures for children with congenital heart disease, the ability to minimize radiation dose has become an increasingly important patient safety issue.
11. According to the Hospital the new pediatric cardiac catheterization laboratory system will enhance the delivery of radiation treatment as follows: *(June 13, 2008, CON Waiver Form 2040, page 6)*
- Improves ready access to advance technology;
 - Improves lower radiation exposure;
 - Improves the ability to perform critical complex interventions safely;
 - Enhances image quality and resolution capability;
 - Enhances patient care, quality and safety; and
 - Enhances clearer images of the heart from different angles, facilitating more efficient diagnosis and treatment of cardiac conditions in the Hospital’s pediatric patients.
12. The Hospital states that the volume of the existing pediatric cardiac catheterization laboratory system is as follows:

	FY 2005	FY 2006	FY 2007	FY 2008 (6 months)
Pediatric Cardiac Catheterization Lab Volume (Cases)	212	210	233	78

(June 13, 2008, CON Waiver Form 2040, page 37)

13. The total capital expenditure for the replacement project is \$5,092,358, which consists of the following components:
 - a) \$798,581 for the associated medical equipment purchase;
 - b) \$1,764,491 for the associated major medical equipment purchase; and
 - c) \$2,529,286 for construction and renovation work associated with the installation of the new equipment.
(June 13, 2008, CON Waiver Form 2040, page 3 and Appendix II)

14. The capital cost of \$1,764,491 for the replacement pediatric cardiac catheterization laboratory system equipment is below the \$3 million threshold used to determine whether a request is eligible to receive a waiver of CON requirements for replacement equipment pursuant to Section 19a-639c, C.G.S.
(June 13, 2008, CON Waiver Form 2040, page 2)

15. The Hospital will fund the proposal through its equity and depreciation funds. *(June 13, 2008, CON Waiver Form 2040, page 4)*

16. The Hospital intends to begin operating the new pediatric cardiac catheterization laboratory system upon CON approval. *(June 13, 2008, CON Waiver Form 2040, page 2)*

17. The Hospital states that there is no proposed change to the operating hours for the pediatric cardiac catheterization laboratory system service. *(June 13, 2008, CON Waiver Form 2040, page 37)*

18. The replacement pediatric cardiac catheterization laboratory system equipment will serve the Hospital's existing patient population and with no anticipated changes in the payer mix due to the proposal. *(June 13, 2008, CON Waiver Form 2040, page 5)*

Rationale

Yale-New Haven Hospital (“Hospital”) is requesting a waiver of Certificate of Need (“CON”) requirements for replacement equipment, pursuant to Section 19a-639c, C.G.S. The Hospital is seeking to replace its existing pediatric cardiac catheterization laboratory system in New Haven and to undertake renovations to accommodate the new equipment. The new pediatric cardiac catheterization laboratory system replacement equipment will be located at 20 York Street in New Haven.

The Hospital is requesting that the existing pediatric cardiac catheterization laboratory equipment system be replaced as the existing equipment is over 11 years old and is at the end of its useful life. The equipment has experienced increasing breakdowns, repairs and maintenances problems. The Hospital indicates that as catheter base therapies have become increasingly complex, requiring longer and potentially more frequent procedures for children with congenital heart disease, the ability to minimize radiation dose has become an increasingly important patient safety issue. The new pediatric cardiac catheterization laboratory system will lower radiation exposure and improve the ability to perform critical complex intervention safely. Additionally, the hospital states that the proposed pediatric cardiac catheterization laboratory replacement will enhance image quality, resolution capability, patient care, quality and safety. The clearer images of the heart from different angles facilitate more efficient diagnosis and treatment of cardiac conditions in the Hospital’s pediatric patients will also be enhanced.

The capital cost for the proposed replacement pediatric cardiac catheterization laboratory system equipment is \$1,764,491 which is below the \$3 million threshold for determining eligibility for a waiver of CON requirements for replacement equipment pursuant to Section 19a-639c, C.G.S. The Hospital will fund the replacement project through its equity and depreciation funds.

Order

Based on the foregoing Findings and Rationale, OHCA has determined that the Yale-New Haven Hospital request for a waiver of CON requirements for replacement equipment in order to replace its existing pediatric cardiac catheterization laboratory system in New Haven, at a total capital cost of \$5,092,358, meets the requirements for waiver of the CON process pursuant to Section 19a-639c, C.G.S. and is hereby Approved subject to the following conditions.

1. This authorization shall expire on June 20, 2009. Should the Hospital's replacement 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 \$5,092,358. 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.
3. With respect to the acquisition of the new pediatric cardiac catheterization laboratory system, the Hospital shall notify OHCA regarding the following information in writing by no later than two months after the system becomes operational:
 - a) The name of the system manufacturer;
 - b) The model name and description of the system; and
 - c) The initial date of the operation of the system.
4. This authorization requires the removal of the Hospital's existing pediatric cardiac catheterization laboratory system for certain disposition, such as sale or salvage, outside of and unrelated to the Hospital's Connecticut service locations. Furthermore, the Hospital shall provide evidence to OHCA of the disposition of the existing pediatric cardiac catheterization laboratory system to be replaced by no later than six months after the replacement system has become operational.
5. Should the Hospital propose any change in the pediatric cardiac catheterization laboratory system service, the Hospital shall file with OHCA a Certificate of Need Determination Request regarding the proposed service change.

Should the Hospital fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional action 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 June 20, 2008

Date

Cristine A. Vogel
Commissioner

CAV: dd