



Office of Health Care Access

Modification of a Previously Authorized Certificate of Need

Applicant:	The Stamford Hospital and New York Presbyterian Healthcare System, Inc.
Modification Docket Number:	07-30374-MDF
Modification Project Description:	A request to modify a previous Certificate of Need authorization in order to increase the authorized capital expenditure by \$2,551,211, from \$5,404,425 to \$7,955,636
Original Project Docket Numbers and Title	Docket Number 04-30374-CON: Establishment of an Elective Angioplasty and Open Heart Surgery Program at The Stamford Hospital
Statutory Reference:	Sections 4-181a(b), Connecticut General Statutes
Filing Date:	August 13, 2007
Hearing Waived	September 4, 2007
Decision Date:	September 10, 2007
Staff	Karen Roberts

Project Description: The Stamford Hospital and New York Presbyterian Healthcare System, Inc. (together “Applicants”) request a modification of the Certificate of Need (“CON”) authorization issued under Docket Number 04-30374-CON in order to increase the authorized capital expenditure by \$2,551,211, from \$5,404,425 to \$7,955,636. The CON under Docket Number 04-30374-CON authorized the Applicants’ proposal to establish an elective angioplasty and open heart surgery program at The Stamford Hospital.

Findings of Fact

1. On January 4, 2006, under Docket Number 04-30374-CON, the Office of Health Care Access (“OHCA”) granted a Certificate of Need (“CON”) to The Stamford Hospital (“TSH” or “Hospital”) and New York Presbyterian Healthcare System, Inc. (“NYPHS”), together referred to as Applicants, to establish an elective angioplasty and open heart surgery program at The Stamford Hospital. Stipulations #1 and #5 of the CON Order states the following:

“1. The Applicants’ request for a CON to establish an elective angioplasty and open-heart surgery program to be located at TSH, at a total capital expenditure of \$5,404,425, is hereby approved.”

“5. TSH shall not exceed the approved total capital expenditure of \$5,404,425. In the event TSH learns of potential cost increases or expects final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised CON project budget. The source of funding for the project will be The Stamford Hospital’s operations and owner equity.”

2. On August 13, 2007, OHCA received the Applicants’ request for an increase in the authorized total capital expenditure, by \$2,551,211, from \$5,404,425 to \$7,955,636. The Applicants provide the following reasons for the request to increase the authorized costs:
 - a. The authorized capital expenditure of \$5,404,425 was based on the assumption that only one new operating room would be constructed while an existing operating room would be renovated to serve as the back-up room for a total of two cardiac operating rooms.
 - b. As the construction and renovation plans for the cardiac operating rooms moved forward, it became apparent to the Applicants that the second operating room would not be at least 600 square feet in size, which is the preferred size of a back-up operating room based on clinical experience of the cardiothoracic surgeons affiliated with the co-applicant, NYPHS. NYPHS has assisted in developing the program’s facilities and protocols.
 - c. A decision was then made to convert the space being occupied by the Hospital’s existing Cystology Room into the second cardiac operating room. This flexibility was created by the Hospital’s ability to utilize an existing mobile cystology machine that could be transported to the other operating rooms for urology procedures in lieu of performing all procedures in a dedicated room.
 - d. The result of the conversion of the Cystology Room was the construction of two new cardiac operating rooms over 600 square feet each, with the main cardiac operating room measuring 725 square feet and the back-up operating room measuring 623 square feet. This reconfiguration also necessitated an expansion of the perfusion room, cardiac operating room storage and substerile space necessary to support the two cardiac operating rooms, such that the total square footage of the combined cardiac operating rooms and support areas will be 1,800 square feet.

- e. In addition, these changes also necessitated revisions to the current mechanical, electrical and medical gas infrastructure systems. These changes included the need for a new stand-alone HVAC system to support the additional square footage, the installation of a redundant HVAC system to serve as an HVAC back-up, modifications to the existing power systems for the surgical suite area and the installation of a new CO₂ manifold to feed both cardiac ORs.
 - f. Additional increased medical equipment costs are related to technological enhancements as well as the construction of the two operating rooms. These changes are:
 - Upgrade of the Video Integration System - \$400,000;
 - Upgrade of the Physiological Monitoring System - \$100,000;
 - Installation of two sets of booms and lights instead of one set - \$140,000.
 - g. The Hospital incurred other additional costs due to the fact that once end-users held discussions on equipment components such as cardiac outpatient monitoring systems as well as arterial blood gas monitoring systems, decisions were made to purchase pieces that were compatible with the hospital's existing clinical systems versus going with a piece-by-piece approach.
(Page 3 of the August 13, 2007 request for modification)
3. The above increased project costs result in an increase in renovation costs by \$1,790,194 and medical equipment costs by \$761,017. *(Page 4 of the August 13, 2007 request for modification)*
 4. The Applicants' indicate that the Hospital will utilize operating funds to cover the increased capital expenditure requested. *(Page 3 of the August 13, 2007 request for modification)*
 5. The Hospital has completed all of the construction necessary to implement the project and has filled many of the key clinical and administrative positions necessary to launch the authorized program. *(Page 5 of the August 13, 2007 request for modification)*
 6. This request will not result in a change in the scope of the project originally reviewed and authorized by OHCA, or in any extension in the CON expiration date for this project.
 7. Stipulations #6 and #10 of the CON Order require the following:
 - "6. TSH shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (**Attachment II**). Data should be submitted to OHCA on a computer disk in either an excel workbook or comma-delimited text file in a format specified by OHCA. The most current version of the Connecticut Cardiac Data Registry includes, but may not be limited to, the elements listed in **Attachment II**. Data must be reported to OHCA thirty (30) calendar days following the end of the quarter. Fiscal Year quarters end December 31st, March 31st, June 30th, and September 30th. Upon receipt, OHCA will check the data's conformance to the required specifications and within ten (10) business days notify TSH in writing of its

evaluation. If OHCA finds questionable material, TSH will have fifteen (15) business days from notification by OHCA to submit a revised dataset for evaluation. All patient-level data submitted to OHCA to satisfy this requirement 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. If TSH does not submit the data elements in the Connecticut Cardiac Data Registry on a quarterly basis, the programs may be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the programs.”

“10. *TSH shall participate in the Society of Thoracic Surgeons Database (STS-DB) database and the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. TSH shall provide OHCA quarterly data reports from STS-DB and ACC-NCDR. Data must be reported to OHCA thirty (30) calendar days subsequent to TSH receiving the reports from the STS and ACC. TSH is required to comply with the STS and ACC/AHA criteria and standards. If TSH determines not to participate in the STS-DB or ACC-NCDR, TSH shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in Attachment III.”*

8. In 2006, OHCA modified a number of cardiac related CON authorizations in order to adjust the Cardiac Data Registry reporting requirements from quarterly filings to annual filings, including the filing of Stamford Hospital’s Primary Angioplasty data. Stamford Hospital currently files its Primary Angioplasty data with OHCA on or by October 30th of each year for the period October 1st to September 30th. (OHCA initiated modification decision issued under DN 06-30176-MDF)

Discussion

OHCA has reviewed this request for a modification to a previously authorized CON and finds that the relationship of the CON authorized under Docket Number 04-30374-CON to Section 19a-637 of the Connecticut General Statutes, is not significantly altered by this request for a modification under Docket Number 07-30374-MDF. The modification proposal does not alter the intended scope or timeframe for the project originally reviewed and acted upon by OHCA and the increased costs appear to be for circumstances that were unanticipated by the Applicants at the time of the original CON filing. The request for an additional \$2,551,211 appears to be reasonable.

In addition, OHCA finds it appropriate to revise Stipulations #6 and #10 of the CON Order in order to change data reporting from a quarterly filing to an annual filing requirement to be consistent with other full service cardiac providers who have received CON authorization and are submitting to the Cardiac Data Registry as well as to be consistent with The Stamford Hospital’s filing of its Primary Angioplasty data to the Cardiac Registry. As such, OHCA is undertaking a revision of Stipulations #6 and #10 to achieve this consistency.

Order

Based on the above discussion and the reasons provided in the Applicants' modification request, OHCA hereby **Grants** the request and allows a modification of the CON Order under Docket Number 04-30374-CON. Stipulations # 1, #5, #6 and #10 of the CON Order under Docket Number 04-30374-CON are modified as follows:

1. The Applicants' request for a CON to establish an elective angioplasty and open-heart surgery program to be located at TSH, at a total capital expenditure of \$7,955,636, is hereby approved.
5. TSH shall not exceed the approved total capital expenditure of \$7,955,636. In the event TSH learns of potential cost increases or expects final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised CON project budget. The source of funding for the project will be The Stamford Hospital's operations and owner equity.
6. TSH shall complete and submit to OHCA on an annual basis the data elements in the Connecticut Cardiac Data Registry (Attachment II) consistent with the filings currently made under Docket Number 04-30176-CON, as modified by Docket Number 06-30176-MDF. Data should be submitted to OHCA on a computer disk in either an excel workbook or comma-delimited text file in a format specified by OHCA. The most current version of the Connecticut Cardiac Data Registry includes, but may not be limited to, the elements listed in Attachment II of the CON Order under Docket Number 04-30374-CON. Data must be reported to OHCA by October 30th of each year for the period October 1st to September 30th of the previous operational year. Upon receipt, OHCA will check the data's conformance to the required specifications and within ten (10) business days notify TSH in writing of its evaluation. If OHCA finds questionable material, TSH will have fifteen (15) business days from notification by OHCA to submit a revised dataset for evaluation. All patient-level data submitted to OHCA to satisfy this requirement 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. If TSH does not submit the data elements in the Connecticut Cardiac Data Registry on a quarterly basis, the programs may be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the programs. In addition to the above, TSH shall make their total aggregated number of diagnostic cardiac catheterizations, primary and elective angioplasty and open heart surgery procedures available to OHCA, upon OHCA's request for such information. In addition, OHCA may revise the due date for the filing of the Cardiac Registry data from the current filing date of October 30th without further modification of the CON authorization if it is determined that the annual filings should be consistent with the start date for the Open Heart Surgery Program or the Elective Angioplasty Program. OHCA will confer with TSH upon such determination.

10. TSH shall participate in the Society of Thoracic Surgeons Database (STS-DB) database and the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. TSH shall provide OHCA annual data reports from STS-DB and ACC-NCDR. Data must be reported to OHCA thirty (30) calendar days subsequent to TSH receiving the reports from the STS and ACC. TSH is required to comply with the STS and ACC/AHA criteria and standards. If TSH determines not to participate in the STS-DB or ACC-NCDR, TSH shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in Attachment III.

All other Stipulations set forth in the CON authorization issued under Docket Number 04-30374-CON, not further modified herein, will remain in full effect. This specifically includes the prohibition of commencement of services until such time as the Hospital has filed all necessary information related to Certificate of Need Stipulations #3 and #4 and OHCA acknowledges compliance with such stipulations.

By Order of the
Office of Health Care Access

Signed by Commission Vogel on September 10, 2007

Date

Cristine A. Vogel
Commissioner

CAV/kr