

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

M. JODI RELL
GOVERNOR

CRISTINE A. VOGEL
COMMISSIONER

June 11, 2009

Mr. David L. Smith
Senior Vice President,
Strategy and Business Development
The Stamford Hospital
30 Shelburne Road
P.O. Box 9317
Stamford, CT 06904-9317

RE: Docket Number 09-30374-MDF: An OHCA-initiated modification of a Certificate of Need issued under Docket Number 04-30374-CON, as modified by DN07-30374-MDF
Establish an Elective Angioplasty and Open Heart Surgery Program at Stamford Hospital

Dear Mr. Smith:

On January 4, 2006, under Docket Number 04-30374-CON, The Stamford Hospital and New York Presbyterian Healthcare System, Inc. (together "Applicants") and the Office of Health Care Access ("OHCA") entered into an Agreed Settlement in which OHCA granted a Certificate of Need to the Applicants pursuant to Section 19a-638 and 19a-639 of the Connecticut General Statutes ("C.G.S") for the establishment of an elective angioplasty and open heart surgery program at The Stamford Hospital ("Hospital" or "TSH"). On September 10, 2007, under Docket Number 07-30374-MDF, OHCA issued a modification of 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 and to alter the quarterly data filing requirements, including the filing to the Connecticut Cardiac Data Registry, to annual data filing requirements. Stipulations #6 and #10 of the modification authorization under Docket Number 07-30374-MDF are currently as follows:

- "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 reinstatement 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.*

The open heart surgery program commenced at TSH on January 3, 2008 and the elective angioplasty program commenced on October 20, 2008. On April 15, 2009, OHCA notified the Applicants that OHCA was initiating a modification process related to this Certificate of Need pursuant to Section 4-181a (b) of the Connecticut General Statutes ("C.G.S.") in order to vacate or modify the language of certain CON Stipulations. In the April 15, 2009 Notice, OHCA stated its intent to vacate Stipulation #6 in order to discontinue TSH's data filings to the Connecticut Cardiac Data Registry and to revise Stipulation #10 in order to clarify the continued filing of ACC-NCDR and STS-DB reports to OHCA. In the April 15, 2009 Notice, OHCA provided a timeframe for the Applicants to provide any comments to OHCA regarding this matter. No comments from the Applicants have been provided to OHCA during the allotted timeframe.

The CON authorization issued under Docket Number 04-30374-CON, as previously modified by DN07-30374-MDF, was a contested case; therefore, a modification under Docket Number 09-30374-MDF is also a contested case, requiring a public hearing unless a waiver is granted. Section 19a-643-45 of OHCA's Regulations allows for a waiver on the grounds that the CON modification is non-substantive, as defined in Section 19a-643-95(3) of OHCA's Regulations. Notice to the public of a waiver of hearing was published in *The Advocate*. On June 3, 2009, OHCA waived the public hearing in this matter, having received no comments during the public comment period.

OHCA has reviewed this modification to a previously authorized CON and finds that the relationship of the CON authorized under Docket Number 04-30374-CON, as previously modified by DN07-30374-MDF, to Section 19a-637, C.G.S. is not altered by this modification under Docket Number 09-30374-MDF.

Based on the reasons above, I find it appropriate to approve this modification of the CON authorized under Docket Number 04-30374-CON, as previously modified by DN07-30374-MDF. Therefore, the OHCA initiated modification under Docket Number 09-30374-MDF is **GRANTED**. Stipulation #6 is hereby vacated. The Stamford Hospital is no longer required to submit patient level data to the Connecticut Cardiac Data Registry.

Stipulation # 10 is vacated and replaced with the following:

10. The Stamford Hospital participates in the American College of Cardiology National Cardiovascular Database Registry (ACC-NCDR) and The Stamford Hospital is required to comply with the ACC/AHA criteria and standards. If in the future, The Stamford Hospital determines not to participate in the ACC-NCDR; The Stamford Hospital shall notify OHCA in a timely manner regarding such decision not to participate and shall continue to comply with the ACC/AHA criteria and standards. As long as The Stamford Hospital participates in ACC-NCDR, The Stamford Hospital is required to submit to OHCA any and all Executive Summary pages from the Institutional Outcomes Reports received by The Stamford Hospital from ACC-NCDR, such Executive Summary containing the PCI Quality Measures, PCI Utilization Measures, and Diagnostic Cath Quality Measures. Any such Executive Summaries received by The Stamford Hospital during the year should be submitted to OHCA by December 31st of each calendar year. Further, The Stamford Hospital shall supply to OHCA, the detail reports from ACC-NCDR to The Stamford Hospital only if OHCA specifically requests such detailed reporting.

In addition, The Stamford Hospital participates in the Society of Thoracic Surgeons Database (STS-DB) database. If in the future, The Stamford Hospital determines not to participate in the STS-DB; The Stamford Hospital shall notify OHCA in a timely manner regarding such decision not to participate. As long as The Stamford Hospital participates in STS-DB, The Stamford Hospital is required to submit to OHCA any and all Regional Outcomes Comparisons received by The Stamford Hospital from STS-DB, such Comparison Reports showing the hospital as compared to the Region. All Regional Outcomes Comparisons received by The Stamford Hospital during the year should be submitted to OHCA by December 31st of each calendar year. Further, The Stamford Hospital shall supply to OHCA the detail reports from STS-DB to The Stamford Hospital only if OHCA specifically requests such detailed reporting.

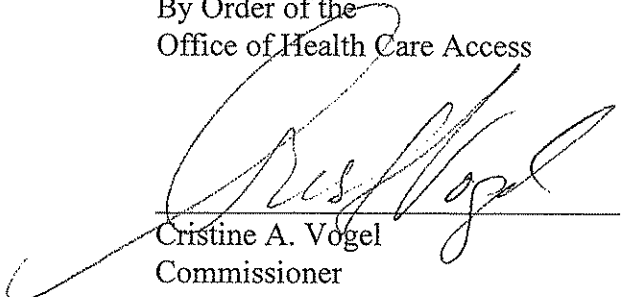
In addition, OHCA finds it appropriate to incorporate a new condition, #15, into the Order for Docket Number 04-30374-CON, as previously modified by Docket Number 07-30374-MDF, as follows:

15. Under a separate Docket Number 04-30176-CON, OHCA issued a Certificate of Need to The Stamford Hospital and New York Presbyterian Healthcare System, Inc. for the establishment of a primary interventional cardiac service to be located at Stamford Hospital pursuant to Section 19a-638 of the Connecticut General Statutes. Stipulation #2 of that CON order set forth a requirement for TSH to file cardiac data with the Connecticut Cardiac Data Registry and Stipulation #5 of that CON order set forth a requirement for TSH to file ACC-NCDR data with OHCA. Such requirements for TSH cardiac data filings previously set forth by Stipulation #2 and #5 within Docket Number 04-30176-CON are hereby fully superseded by the Order under Docket Number 04-30374-CON, as previously modified by DN07-30374-MDF and herein modified under Docket Number 09-30374-MDF.

All other conditions set forth in the CON authorization issued under Docket Number 04-30374-CON, as previously modified by DN07-30374-MDF, not modified herein, will remain in full effect.

By Order of the
Office of Health Care Access

6-11-09
Date


Cristine A. Vogel
Commissioner

CAV/kr

copy: Wayne M. Osten, Sr. VP/Director, New York Presbyterian Healthcare System, Inc. (Co-Applicant)
Marna Borgstrom for the Yale New Haven Heart Health Institute (Yale-New Haven Hospital,
Bridgeport Hospital and Greenwich Hospital), designated Intervenor to DN 04-30374-CON
Susan Davis for St. Vincent's Medical Center, designated Intervenor to DN 04-30374-CON