



STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

M. JODI RELL
GOVERNOR

CRISTINE A. VOGEL
COMMISSIONER

April 16, 2009

Mr. Frank Kelly
President and Chief Executive Officer
Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

RE: Docket Number 09-30143-MDF: An OHCA-initiated modification of a Certificate of Need under Docket Number 03-30143-CON, as modified by Docket Number 06-30143-MDF Open Heart Surgery Program and Angioplasty Program

Dear Mr. Kelly:

On July 23, 2004, under Docket Number 03-30143-CON, the Office of Health Care Access (“OHCA”) and Danbury Hospital (“Hospital”) entered into an Agreed Settlement in which OHCA granted a Certificate of Need (“CON”) to the Hospital pursuant to Sections 19a-638 and 19a-639 of the Connecticut General Statutes for the establishment of an angioplasty and open-heart surgery program at a total capital expenditure of \$5,691,866. The Open Heart Surgery Program commenced at the Hospital on January 14, 2005 and the Angioplasty Program commenced on October 17, 2005.

On May 25, 2006, under Docket Number 06-30143-MDF, OHCA issued a modification of Docket Number 06-30143-MDF, in order to alter the quarterly patient-level data filing to an annual data filing.

On March 4, 2009, OHCA forwarded to you a Notice of Proposed Certificate of Need Modification, which initiated a process under Docket Number 09-30143-MDF to modify the Certificate of Need pursuant to Section 4-181a (b) of the Connecticut General Statutes (“C.G.S.”). In the March 4, 2009 Notice, OHCA stated its intent to vacate Stipulation #7 in order to discontinue Danbury Hospital’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 March 4, 2009 Notice, OHCA provided a timeframe for the Hospital to provide any comments to OHCA regarding this matter. No comments from the Hospital had been provided to OHCA during the allotted timeframe.

Stipulations #7 and #10 of the CON authorization as modified by Docket Number 06-30143-MDF currently state the following:

An Equal Opportunity Employer
410 Capitol Ave., MS#13HCA, P.O.Box 340308, Hartford, CT 06134-0308
Telephone: (860) 418-7001 Toll-Free: 1-800-797-9688
Fax: (860) 418-7053

- “7. *Danbury Hospital shall complete and submit to OHCA on an annual basis the data elements in the Connecticut Cardiac Data Registry (Attachment III). 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 III. Data must be reported to OHCA by January 30th of each year for the period January 1st to December 31st 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 Danbury Hospital in writing of its evaluation. If OHCA finds questionable material, Danbury Hospital 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 the Hospital does not submit the data elements in the Connecticut Cardiac Data Registry on an annual basis, the programs may be terminated. In the event of such a termination, the Hospital shall file a CON for reinstatement of the programs. In addition to the above, Danbury Hospital shall make its total aggregated number of diagnostic cardiac catheterizations and primary and elective angioplasty and open heart surgery procedures available to OHCA, upon OHCA’s request for such information.*”
- “10. *Danbury Hospital 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. The Hospital shall provide OHCA annual data reports from STS-DB and ACC-NCDR. Data must be reported to OHCA thirty (30) calendar days subsequent to the Hospital receiving the reports from the STS and ACC. The Hospital is required to comply with the STS and ACC/AHA criteria and standards. If the Hospital determines not to participate in the STS-DB or ACC-NCDR, the Hospital shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in Attachment III.*”

The CON authorization issued under Docket Number 03-30143-CON was a contested case, therefore, a modification under Docket Number 09-30143-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 Danbury News Times*. On April 14, 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 03-30143-CON to Section 19a-637, C.G.S. is not altered by this modification under Docket Number 09-30143-MDF.

Based on the reasons above, I find it appropriate to approve this modification of the CON authorized under Docket Number 03-30143-CON, as previously modified by Docket Numbers 06-30143-MDF. Therefore, the OHCA initiated modification under Docket Number 09-30143-MDF is **GRANTED**. Stipulation # 7 is hereby vacated. Danbury 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. Danbury Hospital participates in the American College of Cardiology National Cardiovascular Database Registry (ACC-NCDR) and Danbury Hospital is required to comply with the ACC/AHA criteria and standards. If in the future, Danbury Hospital determines not to participate in the ACC-NCDR; Danbury 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 Danbury Hospital participates in ACC-NCDR, Danbury Hospital is required to submit to OHCA any and all Executive Summary pages from the Institutional Outcomes Reports received by Danbury 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 Danbury Hospital during the year should be submitted to OHCA by December 31st of each calendar year. Further, Danbury Hospital shall supply to OHCA the detail reports from ACC-NCDR to Danbury Hospital only if OHCA specifically requests such detailed reporting.

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

All other conditions set forth in the CON authorization issued under Docket Number 03-30143-CON, as previously modified by Docket Numbers 06-30143-MDF, not modified herein, will remain in full effect.

By Order of the
Office of Health Care Access

Signed by Commissioner Vogel on April 16, 2009

Date

Cristine A. Vogel
Commissioner

CAV/kr

Copy: Attorney John Newman for St. Vincent's Medical Center (Intervenor to original CON) by fax copy only
Jean Ahn for Yale-New Haven Hospital (Intervenor to original CON) by fax copy only
Carolyn Salsgiver for Bridgeport Hospital (Intervenor to original CON) by fax copy only