



**STATE OF CONNECTICUT**  
OFFICE OF HEALTH CARE ACCESS

M. JODI RELL  
GOVERNOR

CRISTINE A. VOGEL  
COMMISSIONER

March 31, 2009

Mr. Frank A. Corvino  
President and Chief Executive Officer  
Greenwich Hospital  
5 Perryridge Road  
Greenwich, CT 06830-4697

Ms. Marna Borgstrom  
President and Chief Executive Officer  
Yale-New Haven Hospital  
20 York Street  
New Haven, CT 06510

RE: Docket Number 09-30148-MDF: An OHCA-initiated modification of Docket Number 03-30148-CON, as modified by Docket Numbers 06-30148-MDF and 08-30128-MDF  
Establishment of a Primary Interventional Cardiac Service

Dear Mr. Corvino and Ms. Borgstrom:

On July 8, 2004, under Docket Number 03-30148-CON, Yale-New Haven Hospital, Bridgeport Hospital<sup>1</sup> and Greenwich Hospital d/b/a Yale-New Haven Health Heart Institute and collectively referred to herein as "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 of the Connecticut General Statutes for a three-year demonstration project for the establishment of a primary interventional cardiac service to be located at Greenwich Hospital. Primary interventional cardiac services commenced at Greenwich Hospital on February 28, 2005.

On May 23, 2006 under Docket Number 06-30148-CON, OHCA issued a modification of Docket Number 03-30148-CON to alter the quarterly data filing requirement to the Connecticut Cardiac Data Registry to an annual data filing requirement. On July 25, 2008, OHCA and the Applicants entered into an Agreed Settlement under Docket Number 08-30148-MDF in order to modify the CON and vacate Stipulations #3, #4 and #5 thereby allowing permanent status of the Certificate of Need.

On March 12, 2009, OHCA forwarded to you a Notice of Proposed Certificate of Need Modification, which initiated a process under Docket Number 09-30148-MDF to modify the Certificate of Need, pursuant to Section 4-181a (b) of the Connecticut General Statutes. In the March 12, 2009 Notice, OHCA stated its intent to vacate Stipulation # 2 in order to discontinue Greenwich Hospital data filings to the Connecticut Cardiac Data Registry; to vacate Stipulations #6 and #8 and to revise Stipulation #7 in

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<sup>1</sup> Ms. Borgstrom is provided this Notice by OHCA for both Yale-New Haven Hospital and Bridgeport Hospital.

order to clarify the filing of ACC-NCDR reports to OHCA<sup>2</sup>. In the March 12, 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.

Stipulations #2, #6 and #7 of the CON authorization as modified by Docket Number 06-30148-MDF state the following:

- “2. *Greenwich Hospital shall complete and submit to OHCA on an annual 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 by April 30<sup>th</sup> of each year for the period April 1<sup>st</sup> to March 31<sup>st</sup> 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 Greenwich Hospital in writing of its evaluation. If OHCA finds questionable material, Greenwich 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 Greenwich Hospital does not submit the above data to the Cardiac Data Registry on annual basis, the primary angioplasty program shall be terminated. In addition to the above, Greenwich Hospital shall make its total aggregated number of diagnostic cardiac catheterizations and primary PCI procedures available to OHCA, upon OHCA's request for such information.”*
  
- “6. *Greenwich Hospital shall participate in the C-PORT registry and is required to comply with the patient eligibility and identification, guidelines for clinical care, standards for facilities and care providers and staff training, including care plan and logistics development and quality and error management, as stated in the Manual of Operation and as specified in Attachment I. Greenwich Hospital shall provide OHCA annual data reports through such registry for the purposes of monitoring and quality assurance. If Greenwich Hospital determines not to participate in the C-PORT registry or the C-PORT-registry no longer exists, Greenwich Hospital shall notify OHCA immediately, and continue to comply with the C-PORT guidelines and protocols.”*
  
7. *Greenwich Hospital shall participate in the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. The Applicants shall provide OHCA annual data reports from the ACC-NCDR. These reports shall be submitted to OHCA at the same time that the Connecticut Cardiac Data Registry data is filed. Greenwich Hospital is required to comply with all the ACC/AHA criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery. If Greenwich Hospital determines not to participate in the ACC-NCDR, Greenwich Hospital shall notify OHCA immediately, and continue to comply with the ACC/AHA criteria and standards.*

Stipulation #8 of the CON authorization under Docket Number 03-30148-CON states the following:

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<sup>2</sup> According to OHCA's record under Docket Number 03-30148-CON, Greenwich Hospital has not begun its participation in ACC-NCDR but has stated its intent to do so.

“8. *Greenwich Hospital shall report to OHCA documenting compliance with the ACC/AHA general exclusion criteria for invasive procedures, performance of primary PCI in hospitals without cardiac surgery capabilities, and selection of patients appropriate for primary PCI or transfer to a full-service cardiac center. If Greenwich Hospital does not comply with the ACC/AHA criteria and standards and/or the C-PORT guidelines, Greenwich Hospital’s primary PCI program shall be terminated.*”

As previously noted in the March 12, 2009 Notice, OHCA considers such proposed change to be a non-substantive change and OHCA stated its intent not to schedule and convene a hearing related to this modification process under Docket Number 09-30148-MDF. OHCA has reviewed this modification to a previously authorized CON and finds that the relationship of the CON authorized under Docket Number 03-30148-CON to Section 19a-637, C.G.S. is not altered by this modification under Docket Number 09-30148-MDF.

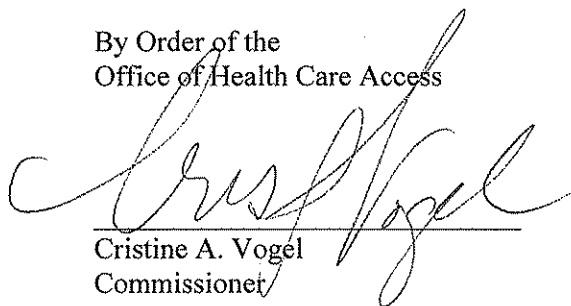
Based on the reasons above, I find it appropriate to approve this modification of the CON authorized under Docket Number 03-30148-CON, as previously modified by Docket Numbers 06-30207-MDF and 08-30148-MDF. Therefore, the OHCA initiated modification under Docket Number 09-30148-MDF is **GRANTED**. Stipulations # 2, #6 and #8 are hereby vacated. Greenwich Hospital is no longer required to submit patient level data to the Connecticut Cardiac Data Registry. Stipulation # 7 is vacated and replaced with the following:

7. Greenwich Hospital shall participate in the American College of Cardiology National Cardiovascular Database Registry (ACC-NCDR) and Greenwich Hospital is required to comply with the ACC/AHA criteria and standards. If Greenwich Hospital determines not to participate in the ACC-NCDR, Greenwich 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.

If Greenwich Hospital does participate in ACC-NCDR, Greenwich Hospital is required to submit to OHCA any and all Executive Summary pages from the Institutional Outcomes Reports received by Greenwich 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 Greenwich Hospital during the year should be submitted to OHCA by December 31<sup>st</sup> of each calendar year. Further, Greenwich Hospital shall supply to OHCA the detail reports from ACC-NCDR to Greenwich Hospital only if OHCA specifically requests such detailed reporting.

All other conditions set forth in the CON authorization issued under Docket Number 03-30148-CON, as previously modified by Docket Numbers 06-30207-MDF and 08-30148-MDF, not modified herein, will remain in full effect.

By Order of the  
Office of Health Care Access



Cristine A. Vogel  
Commissioner

3-31-09  
Date