

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

M. JODI RELL
GOVERNOR

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COMMISSIONER

March 20, 2009

Daniel Rissi, M.D., Vice President
Chief Medical & Clinical Operations Officer
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320

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

RE: **Docket Number 08-30297-MDF:** An OHCA initiated modification of Certificate of Need Docket Number 04-30297-CON, as modified by Docket Number 06-30297-MDF Establishment of a Primary Interventional Cardiac Service at L&M Hospital

Dear Dr. Rissi and Ms. Borgstrom:

On June 1, 2005, under Docket Number 04-30297-CON, Lawrence and Memorial Hospital ("L&M") and Yale-New Haven Hospital ("together 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 the establishment of a primary interventional cardiac service to be located at L&M. The authorized primary interventional cardiac services initially commenced at L&M on January 27, 2006¹. On May 25, 2006, under Docket Number 06-30297-MDF, OHCA issued a modification of Docket Number 04-30297-CON to alter the quarterly data filing requirement to the Connecticut Cardiac Data Registry to an annual data filing requirement.

On December 18, 2008, OHCA received the Applicants' request for a modification of Docket Number 04-30297-CON in order to relieve the Applicants of the requirements of Stipulations #7 and #8 due to the revised model of interventionalist call coverage. Further information was received on February 3, 2009, and the modification request was deemed complete under Docket Number 08-30297-MDF. Stipulations #7 and #8 are as follows:

"7. *The Applicants will contract with a second on-site interventional cardiologist for the proposed PAMI program who will begin performing PAMIs' at L&M upon Dr. Fiengo performing 70 cumulative angioplasty procedures at L&M. The interventional cardiologist must be fully credentialed and have the following qualifications:*

¹ The primary interventional cardiac program was temporarily suspended from September 1, 2006 to May 2, 2008.

- *Board-Certified in interventional cardiology*
- *Maintains a Connecticut license and admitting privileges at both L&M and YNHH*
- *Meets or exceeds the AHA/ACC minimum operator volume standards for PCI for the past 2 years.*

The Applicants shall provide the CV of the additional interventional cardiologist prior to performance of primary angioplasties at L&M. OHCA shall acknowledge receipt and acceptance of the CV prior to performance of PAMIs by the physician.”

- “8. *The Applicants shall report to OHCA documenting compliance with the operating call schedule. The Applicants shall provide documentation that on call YSMCG cardiologists initiate the procedure within 40 minutes of call.”*

On February 24, 2009, OHCA forwarded to you a Notice of OHCA initiated changes to the pending modification request pursuant to Section 4-181a (b) of the Connecticut General Statutes. In the February 24, 2009 Notice, OHCA stated its intent to vacate Stipulations #4 and 6, to vacate Stipulation #2 in order to discontinue L&M’s data filings to the Connecticut Cardiac Data Registry and to replace it with a requirement to file a one-year utilization report subsequent to the completion of the current second year of operation, and to revise the wording of Stipulation #5 in order to clarify the continued filing of ACC-NCDR reports to OHCA.

Condition #2, #4, #5 and #6 of the CON authorization under Docket Number 04-30297-MDF, as subsequently modified by Docket Number 06-30297-MDF, state the following:

- “2. *L&M 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 30th of each year for the period April 1st to March 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 L&M in writing of its evaluation. If OHCA finds questionable material, L&M 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 L&M does not submit the above data to the Cardiac Data Registry on an annual basis, the primary angioplasty program shall be terminated. In the event of such a termination, L&M shall file a CON for the reinstatement of the program. In addition to the above, Lawrence & Memorial shall make its total aggregated number of diagnostic cardiac catheterizations and primary PCI procedures available to OHCA, upon OHCA’s request for such information.”*

- “4. *L&M 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. L&M shall provide OHCA annual data reports through such registry for the purposes of monitoring and quality assurance. If L&M determines not to participate in the C-PORT registry or the C-PORT registry no longer exists, L&M shall notify OHCA immediately, and continue to comply with the C-PORT guidelines and protocols.”

5. *L&M shall participate in the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. L&M 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. L&M 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 L&M determines not to participate in the ACC-NCDR, L&M shall notify OHCA immediately, and continue to comply with the ACC/AHA criteria and standards.*
6. *L&M 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 the ACC/AHA criteria and standards and/or the C-PORT guidelines are not met, Lawrence and Memorial Hospital’s primary PCI program shall be terminated. In the event of such a termination, L&M shall file a CON for the reinstatement of the program.”*

In the February 24, 2009 Notice, OHCA provided a timeframe for the Applicants to provide any comments to OHCA regarding this matter. No comments from the Applicants had been provided to OHCA during the allotted timeframe. As previously noted in the February 14, 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 09-30297-MDF. OHCA has reviewed this modification to a previously authorized CON and finds that the relationship of the CON authorized under Docket Number 04-30297-CON to Section 19a-637, C.G.S. is not altered by this modification under Docket Number 09-30297-MDF.

Based on the reasons above and on the rationale within the Applicants’ modification request, I find it appropriate to approve this modification of the CON authorized under Docket Number 04-30297-CON, as previously modified by Docket Number 06-30297-MDF. Therefore, the request for modification as further amended by OHCA is hereby **GRANTED**.

Stipulations #4, #6, 7 and #8 are hereby vacated in their entirety.

Lawrence & Memorial Hospital is no longer required to submit patient level data to the Connecticut Cardiac Data Registry and **Stipulation #2** is hereby vacated and replaced with the following:

2. Lawrence & Memorial Hospital is required to file by May 15, 2009, a utilization report subsequent to the completion of the current second full year of operation. Such report will not contain any patient record level data and will be in the following format:

	Total Number of Patients receiving a PCI Procedure for the period May 2, 2008 – May 1, 2009	Total Number of PCI Procedures performed during the period May 2, 2008 – May 1, 2009*
Month 1 (May 2, 2008 – June 1, 2008)		
Month 2 (June 2, 2008 – July 1, 2008)		
Month 3 (July 2, 2008 – August 1, 2008)		
Month 4 ...		
Operational Year Total		

**The Hospital should identify the procedure codes used to compile this table, but the Hospital does not need to file the total patient and procedure numbers by specific procedure code.

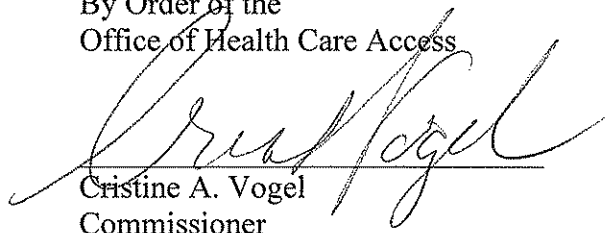
Stipulation #5 is hereby vacated and replaced with the following:

- The Applicants agree that it is the intent of Lawrence & Memorial Hospital to continue to participate in the American College of Cardiology National Cardiovascular Database Registry (ACC-NCDR). Lawrence & Memorial Hospital is required to comply with the ACC/AHA criteria and standards. If Lawrence & Memorial Hospital determines not to participate in the ACC-NCDR, Lawrence & Memorial 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 Lawrence & Memorial Hospital does participate in ACC-NCDR, Lawrence & Memorial Hospital is required to submit to OHCA any and all Executive Summary pages from the Institutional Outcomes Reports received by Lawrence & Memorial 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 Lawrence & Memorial Hospital during the year should be submitted to OHCA by December 31st of each calendar year. Further, Lawrence & Memorial Hospital shall supply to OHCA the detail reports from ACC-NCDR to Lawrence & Memorial Hospital only if OHCA specifically requests such detailed reporting.

All other conditions set forth in the CON authorization issued under Docket Number 04-30297-CON, as previously modified by Docket Number 06-30297-MDF, not further modified herein, will remain in full effect.

By Order of the
 Office of Health Care Access



Cristine A. Vogel
 Commissioner

3-20-09
 Date

CAV/kr