



**Office of Health Care Access
Request for Modification of a Previously
Authorized Certificate of Need**

AGREED SETTLEMENT

Applicants: Yale-New Haven Hospital, Bridgeport Hospital and Greenwich Hospital d/b/a Yale-New Haven Health Heart Institute

Modification Docket Number: 08-30148-MDF

Description of Proposed Modification Request: A request to modify a previous Certificate of Need authorization in order to allow the interventional cardiac service at Greenwich Hospital, previously authorized by Agreed Settlement as a three year demonstration project only, to be recognized by OHCA as a permanent service of Greenwich Hospital

Original Project Docket Numbers and Title Docket Number 03-30148-CON as previously modified by Docket Number 06-30148-MDF
The Establishment of Primary Interventional Cardiac Services at Greenwich Hospital in Greenwich

Statutory Reference: Sections 4-181a(b), Connecticut General Statutes

Filing Date: March 6, 2008

Hearing Date: April 30, 2008

Decision Date: July 25, 2008

Staff Karen Roberts

Project Description: Yale-New Haven Hospital, Bridgeport Hospital and Greenwich Hospital d/b/a Yale-New Haven Health Heart Institute (“Applicants”) request a modification of the Certificate of Need authorization issued under Docket Number 03-30148-CON, as previously modified by Docket Number 06-30148-MDF, to allow the interventional cardiac service at Greenwich Hospital, previously authorized by Agreed Settlement as a three year demonstration project only, to be recognized by OHCA as a permanent service of Greenwich Hospital.

Nature of Proceedings: On March 6, 2008, the Office of Health Care Access (“OHCA”) received a request for modification of the previous CON decision from Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital d/b/a Yale-New Haven Health Heart Institute (“Applicants”). The Applicants request a modification of the Certificate of Need authorization issued under Docket Number 03-30148-CON, as previously modified by Docket Number 06-30148-MDF, to allow the interventional cardiac service at Greenwich Hospital, previously authorized by Agreed Settlement as a three year demonstration project only, to be recognized by OHCA as a permanent service of Greenwich Hospital.

OHCA is allowed to consider a modification to a previous agency final decision upon a showing of changed conditions pursuant to Section 4-181a (b) of the Connecticut General Statutes. Further, the ability of the Applicants to seek a modification of this CON to request permanent status based upon three year procedural volume was specifically set forth in Agreed Settlement Stipulation #5 under Docket Number 03-30148-CON. A public hearing regarding this matter was held on April 30, 2008. On April 3, 2008, the Applicant was notified of the date, time, and place of the hearing. A notice was published in The Greenwich Times on April 7, 2008. Commissioner Cristine A. Vogel served as Presiding Officer in this matter.

The Presiding Officer heard testimony from witnesses representing the Applicants. In rendering this decision, the Presiding Officer considered the entire record of the proceeding. OHCA’s authority to review and determine whether any change of conditions has occurred is established by Section 4-181a (b), C.G.S.

Findings of Fact

1. On July 8, 2004, the Office of Health Care Access (“OHCA”) entered into an Agreed Settlement with Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital d/b/a Yale-New Haven Health Heart Institute (“Applicants”) for the establishment of Primary Interventional Cardiac Services at Greenwich Hospital (“GH”) in Greenwich as a three year demonstration project. Stipulations #3, #4 and #5 of the CON authorization state the following:

“3. OHCA and the Applicants agree that this CON is granted for and in effect for an initial period of three (3) years, starting on the date of the performance of the first primary angioplasty procedure, in order for the Applicants to validate that the program can achieve the utilization that has been projected in the CON proposal. Thereafter, the continuation of this CON shall be governed by Stipulation #6. The Applicants shall schedule quarterly meetings at and with OHCA, regarding the implementation and progress of the primary angioplasty program.”

“4. The Applicants agree that they must demonstrate that the service is achieving sufficient utilization for the three years of the authorized project period. Sufficient utilization may be defined as achieving, at least:

- *FY 2005 40 Primary Angioplasty Procedures*
- *FY 2006 42 Primary Angioplasty Procedures*
- *FY 2007 44 Primary Angioplasty Procedures”¹*

“5. *The Applicants agree to file with OHCA at the end of the initial project period, a request for modification of this CON authorization under Docket Number 03-30148 to continue the operation of this program. Such request shall be filed within thirty (30) calendar days subsequent to the end of the third full fiscal year. The request shall be for the continuation of the service with permanent CON authorization status. The Applicants will be allowed to continue the primary angioplasty program until such time as OHCA reviews the request for continuation and takes action upon the request. Continuation of the primary angioplasty program with permanent CON authorization status shall be reviewed and determined based upon the Applicants fully demonstrating to OHCA that the primary angioplasty program is achieving sufficient utilization levels (as identified above in Stipulation #5).*”

(Source: July 8, 2004 Agreed Settlement under Docket Number 03-30148-CON)

2. OHCA made the following statements in its Decision Rationale specific to the creation of this demonstration project:

“... the low volume of diagnostic catheterization that the cardiac catheterization laboratory has generated since its inception in 1988 is troubling to OHCA, and OHCA seeks assurance that the projected volume of primary angioplasty procedures for the proposed program will be met. The Applicants and members of the Greenwich community presented compelling evidence and testimony to OHCA which demonstrated a clear public need for the primary angioplasty program, however, OHCA desires that the Applicants more fully demonstrate their ability to realize the projected utilization statistics. Therefore, OHCA concludes that the Applicants should be authorized to offer a primary angioplasty program at Greenwich Hospital for a limited period of three years. The provision of the program for three years will provide the Applicants with adequate time to validate that the program can achieve the utilization that was projected in the proposal. The program will be allowed to continue if the projections are met. If the Applicants are unable to achieve these volumes at the end of three years, the program will be terminated. This approach assures the public of sound professional and clinical expertise. OHCA believes that the phased in approach of this proposal will guarantee the availability of a quality primary angioplasty program for the citizens of the Greenwich area.”

(Source: July 8, 2004 Agreed Settlement under Docket Number 03-30148-CON)

3. Attachment #1 of the Agreed Settlement under Docket Number 03-30148-CON states, in part, that Primary angioplasty would be performed at GH safely and efficiently by meeting ACC/AHA criteria and standards and C-PORT guidelines through the following:

¹ The target numbers set forth by OHCA in Stipulation #4 were based upon the Applicants’ utilization projections during the CON application process in 2003 – 2004.

“e) Participating interventional cardiologists must perform at least 75 interventional procedures per year and the program must perform at least 36 primary angioplasty procedures per year”

(Source: July 8, 2004 Agreed Settlement under Docket Number 03-30148-CON)

4. The Yale New Haven Health Heart Institute Primary Angioplasty Program at Greenwich Hospital was initiated on February 14, 2005². *(Source: April 27, 2005 letter to OHCA from GH)*
5. On May 23, 2006 under Docket Number 06-30148-CON, OHCA issued a modification of the Agreed Settlement under Docket Number 03-30148-CON primarily to change the Connecticut Cardiac Data Registry filings required under Docket Number 03-30148-CON from quarterly filings to annual filings. In that modification action, OHCA also amended the wording of Stipulations #4 and #5³, as follows:

“4. The Applicants agree that they must demonstrate that the service is achieving sufficient utilization for the three years of the authorized project period. Sufficient utilization may be defined as achieving, at least:

<i>First Operational Year</i>	<i>40 Primary Angioplasty Procedures</i>
<i>Second Operational Year</i>	<i>42 Primary Angioplasty Procedures</i>
<i>Third Operational Year</i>	<i>44 Primary Angioplasty Procedures”</i>

“5. The Applicants agree to file with OHCA at the end of the initial project period, a request for modification of this CON authorization under Docket Number 03-30148-CON to continue the operation of this program. Such request shall be filed within thirty (30) calendar days subsequent to the end of the third full operational year. The request shall be for the continuation of the service with permanent CON authorization status. The Applicants will be allowed to continue the primary angioplasty program until such time as OHCA reviews the request for continuation and takes action upon the request. Continuation of the primary angioplasty program with permanent CON authorization status shall be reviewed and determined based upon the Applicants fully demonstrating to OHCA that the primary angioplasty program is achieving sufficient utilization levels (as identified above in Stipulation #4).”

6. According to GH’s filings into the Connecticut Cardiac Data Registry, GH’s program served its first Primary Angioplasty patient on February 28, 2005. This is accepted by OHCA as the start of the three year initial operational period. *(Source: Connecticut Cardiac Data Registry)*
7. On March 6, 2008, under Docket Number 08-30148-MDF, the Applicants filed a request for modification of the Agreed Settlement under Docket Number 03-30148-CON. The Applicants are seeking permanent approval of its primary angioplasty program.
8. In its March 6, 2008 request, the Applicants indicate that Greenwich Hospital performed the following number of primary angioplasty procedures for the initial three year period:

² The term Initiated in this finding means that the service became available for patient use on this date. No patients were served on this date so that date is not the start of the demonstration project operational period.

³ Stipulations #4 and #5 were amended to change the timeframe from a Fiscal Year to an Operational Year.

Year 1 (2/28/2005 – 2/27/2005)	33 procedures
Year 2 (2/28/2006 – 2/27/2007)	40 procedures
Year 3 (2/28/2007 – 2/27/2008)	<u>39</u> procedures

Total for three year period 112 procedures
(Source: March 6, 2008 Modification Request, Cover Letter and Page 7)

9. The Applicants indicate that during the three year period, three patients had to be transferred out of GH to another facility for primary angioplasty because a cardiac catheterization procedure was already underway in the cardiac catheterization room and therefore the room was unavailable. A new special procedure room with cardiac catheterization capabilities was opened at GH in December 2007. The availability of this room “nearly eliminates the need to transfer GH patients who are candidates for primary angioplasty to another facility.” Had this second room been available during the three year period, GH would have experienced 115 total primary angioplasty procedures⁴. (Source: March 6, 2008 Modification Request, Page 7)

10. The Applicants make the following statements in its March 6, 2008 modification request:

- a. *“The program ... has achieved its goal of providing immediate, life-saving access to interventional cardiac services for appropriate patients presenting with ST-segment elevation and left bundle branch blockage (LBBB) myocardial infarction in accordance with the American College of Cardiology/American Heart Association patient selection criteria. ... In addition, the program has enhanced the overall quality of care for acute cardiac patients at Greenwich Hospital through a comprehensive risk stratification process, has enhanced the Hospital’s diagnostic cardiac catheterization service, and has provided the community and GH service area with an elevated level of access for their emergent cardiac care needs.”*
- b. *“GH’s primary angioplasty program meets or exceeds national quality benchmarks. The program’s door-to-reperfusion times are well within and even exceed the American College of Cardiology/American Heart Association (ACC/AHA) recommended goal. ... From the program’s start in February 2005 until June 2006, 74% of GH’s primary angioplasty patients had door-to-reperfusion times of 120 minutes or less. ... Since July 2006, 86% of GH primary angioplasty patients have had door-to-reperfusion times of 90 minutes or less. The program’s overall average door-to-reperfusion time for all patients since the program started is 87 minutes.”*
- c. *“... the overall quality of care for unstable cardiac patients at Greenwich Hospital has been enhanced as a result of the primary angioplasty program. All patients who present with acute cardiac symptoms now receive urgent risk stratification by an interventional cardiologist; this service is available 24 hours per day, seven days per week. Patients experiencing acute cardiac symptoms trigger an “MI alert”, a method by which the on-call interventional cardiologist provides an immediate evaluation and triage, resulting in urgent diagnosis and treatment, including a possible urgent*

⁴ The transfers of these three primary angioplasty candidates occurred as follows: The first transfer occurred in 2nd quarter of Year Two, the second transfer occurred in 2nd quarter of Year Three and the third transfer occurred in 3rd quarter of Year Three. (Source: April 25, 2008 Response to Interrogatories, Page 7)

diagnostic cardiac catheterization. Since 2005, approximately 180 patients have triggered an “MI alert”; of these, 112 patients have received primary angioplasty. Of the patients who did not require primary angioplasty, the risk stratification process revealed that some patients required bypass surgery or had conditions such as pericarditis that could be medically managed and did not call for an immediate intervention.” (Source: March 6, 2008 Modification Request, Pages 4-7)

11. The Applicants indicate that in addition to the 112 patients who received primary angioplasty at GH during the three year operational period, there were also 66 patients who were triaged for emergent cardiac catheterization but did not require a primary angioplasty at Greenwich Hospital. The Applicants provide the following Table to demonstrate the disposition of these 66 patients:

Table 1: Disposition of Patients Triaged for Emergent Cardiac Catheterization

Disposition	Year 1	Year 2	Year 3	Total
Number transferred for cardiac bypass surgery	7 of 24 (29.2%)	4 of 17 (23.5%)	8 of 25 (32.0%)	19 of 66 (28.8%)
Number transferred for urgent angioplasty (non-STEMI ⁵)	6 of 24 (25.0%)	4 of 17 (23.5%)	5 of 25 (20.0%)	15 of 66 (22.7%)
Number stabilized and treated medically	3 of 24 (12.5%)	5 of 17 (29.4%)	7 of 25 (28.0%)	15 of 66 (22.7%)
Number with non-ACS ⁶ diagnosis such as pericarditis	8 of 24 (33.3%)	4 of 17 (23.5%)	5 of 25 (20.0%)	17 of 66 (25.6%)

(Source: April 25, 2008 Response to Interrogatories, Page 6)

12. The Applicants indicate that the incidence of adverse outcomes is very low for the three-year period. Although two of the 112 emergency angioplasty cases had percutaneous entry site bleeding complications, neither required surgical correction. During the three-year period, there was one episode of stent thrombosis, which occurred post-discharge. No instances occurred of in-hospital acute vessel closure, stroke, episodes of acute renal failure, patients requiring emergency bypass surgery or in-catheterization lab mortalities. *(Source: April 25, 2008 Response to Interrogatories, Page 7)*
13. The Applicants indicate that the program had an angiographic success rate of 96% (108 of 112 total), which means that of the program’s primary angioplasty patients, 96% had a final outcome stenosis of less than 20%. The Applicants state that “*Angiographic success is traditionally described as less than 50% residual stenosis. However, in the modern stent era, less than 20% is a reasonable target.*” The Applicants further state that “*ACC/AHA guidelines recommend 95% success rate for elective PCI cases.*” *(Source: April 25, 2008 Response to Interrogatories, Page 8)*

⁵ STEMI is ST Segment Elevation Myocardial Infarction

⁶ ACS is Acute Coronary Syndrome

14. The interventional cardiologists performing primary angioplasty at Greenwich Hospital perform angioplasty procedures (primary and elective) at several other facilities in Connecticut. The following Table demonstrates the total number of procedures at all facilities in total for the past three years:

Table 2: Interventionalist Volume at Greenwich Hospital and other facilities past three years

Interventionalist (A, B, C, etc.)	Number at Greenwich Hospital for 3 year period	Number all facilities (including GH) for same period****	Average per year using total facility #
A	4	497	166
B	3	399	133
C	9	530	176
D	7	552	184
E	2	154	N/A *
F**	61	291	97
G	6	544	181
H	4	397	132
I	15	292	97
J	1	88	N/A ***
K	0	30	N/A ***
Total	112	3,774	

* Medical Leave of Absence during three-year period

** Medical Director of the Greenwich Hospital Primary Angioplasty Program

*** Non-Applicable as start date was in 2007

**** Other facilities information uses calendar year (Jan – Dec) as opposed to the Greenwich Hospital column which reflects the demonstration project operational year (Feb 28th –Feb 27th).

15. As previously noted in Finding of Fact #7 above, the Hospital reports the following primary angioplasty procedure volume for Year Three of the operational period:

Year 3 (2/28/2007 – 2/27/2008) 39 procedures

Greenwich Hospital’s data filings into the Connecticut Cardiac Data Registry result in a Year Three figure of 38 procedures using the specific Data Registry filing parameters. When asked to explain the difference between the 39 procedures identified in the modification request and the 38 procedures which results from the Data Registry submission, the Hospital provides the following explanation: *“The difference of one PAMI patient in Year Three is identified as a case ... where a primary angioplasty procedure was performed on a patient without angiographic success. The patient was stabilized and had a favorable hospital course. The discharge coding abstract for this patient, however, does not list the primary angioplasty as the principle procedure and therefore, according to the registry’s guidelines, the procedure is not reflected as a primary angioplasty in the cardiac registry file.”*

(Source: June 5, 2008 letter from the Applicants to OHCA)

Discussion

Section 4-181a (b) of the Connecticut General Statutes allows for consideration of a modification to a previous final decision of the Agency upon a showing of changed conditions. In this particular matter, the ability of the Applicants to file a modification request for permanent status, and for OHCA to review and take action upon such request, was specifically set forth and agreed to within Stipulation #5 of the Agreed Settlement under Docket Number 03-30148-CON.

At the outset of this discussion, OHCA notes that the number of procedures performed at Greenwich Hospital (“GH”) during the initial three year period of February 28, 2005 through February 27, 2008 is slightly less than the number of procedures which OHCA set forth as the demonstration project annual target numbers in Stipulation #4 and which OHCA may use in defining the achievement of sufficient utilization for purposes of program continuation. The target numbers were based upon the Applicant’s own projections in the initial CON application in 2003 and 2004. In Year One, GH was to have achieved 40 procedures and instead achieved 33 procedures, seven less. In Year Two, GH was to have achieved 42 procedures and instead achieved 40 procedures, two less. In Year Three, GH was to have achieved 44 procedures and instead achieved 39 procedures, five less.

In terms of attainment of AHA/ACC institutional utilization standards, GH had performed in Years Two and Three in excess of the 36 primary angioplasty procedures recommended as a minimum annual number for Years Two and Three. The interventional cardiologists who have been performing the procedures at GH over the three year period of time have performed well in excess of the 75 procedures recommended as a minimum standard by the AHA/ACC. Although the AHA/ACC standards for institutional and operator minimums are not set forth by OHCA as the specific benchmarks for program continuation, these are noteworthy achievements for this program.

The continuation of this program, however, is reviewed by OHCA in terms of how well Greenwich Hospital has achieved sufficient utilization as may be defined by OHCA using the target numbers set forth in Stipulation #4. On that point OHCA determines that sufficient and good cause has been demonstrated in this matter for OHCA to conclude that the program is achieving sufficient utilization toward validation of the program’s continuing existence on a permanent basis. OHCA finds that allowing the continuation of the program based on the very close proximity of the actual volume amounts to the amounts projected by the Hospital, which became the demonstration project target numbers, is both reasonable and justifiable, and clearly in the best interest of the patients served by Greenwich Hospital.

OHCA concludes that the actualization and attainment over the past three years, of a sufficient number of primary angioplasty procedures, satisfactorily close to the demonstration project annual target numbers, is an adequate demonstration of change in conditions to allow a modification under Section 4-181a(b) of the Connecticut General Statutes.

Order

NOW, THEREFORE, the Office of Health Care Access (“OHCA”) and Yale-New-Haven Hospital, Bridgeport Hospital and Greenwich Hospital d/b/a Yale-New Haven Health Heart Institute (the “Applicants”) hereby stipulate and agree to the terms of settlement with respect to the Applicants’ modification request, as follows:

- a) The Applicants’ request to modify the CON authorized under Docket Number 03-30148-CON, as previously modified by Docket Number 06-30148-MDF in order to allow permanent status of the Certificate of Need is hereby approved. The demonstration project is determined to be concluded and Stipulations #3, #4 and #5 are vacated.
- b) The Applicants agree that if Greenwich Hospital does not perform the ACC/AHA recommended minimum number of annual institutional volumes for the period February 28, 2008 through February 27, 2009, Greenwich Hospital shall submit monthly reports of primary angioplasty volume arrayed by physician to OHCA for a one year period commencing in March 2009. If by the end of the second 12-month period (February 28, 2009 through February 27, 2010), the ACC/AHA institutional annual volumes continue to be unmet at and by Greenwich Hospital, the Applicants’ agree that the primary PCI program will be terminated. In the event of such termination, Greenwich Hospital shall file a CON for any proposed reinstatement of the program.
- c) This Agreed Settlement is an Order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at the Applicants’ expense, if the Applicants fail to comply with its terms.
- d) All other conditions set forth in the CON authorization issued under Docket Number 03-30148-CON, as previously modified by Docket Number 06-30148-MDF, not modified or vacated herein, will remain in full effect.

Signed by Frank Corvino on July 24, 2008

Date

Duly Authorized Agent for
Greenwich Hospital

Signed by Marna Borgstrom on July 23, 2008

Date

Duly Authorized Agent for
Yale-New Haven Hospital

Signed by Marna Borgstrom on July 23, 2008

Date

Duly Authorized Agent for
Bridgeport Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on July 25, 2008.

Signed by Commissioner Vogel on July 25, 2008

Date

Cristine A. Vogel
Commissioner
Office of Health Care Access

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