Office of Health Care Access
Certificate of Need Application

Final Decision

Applicant:	**Greenwich Hospital and Yale-New Haven Hospital**
Docket Number:	**08-31210-CON**
Project Title:	**Establish and Operate a Five Year Demonstration Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital**
Statutory Reference:	**Section 19a-638 of the Connecticut General Statutes**
Filing Date:	**January 23, 2009**
Hearing Date:	**February 24, 2009**
Presiding Officer:	**Cristine A. Vogel, Commissioner**
Intervenor:	**The Stamford Hospital**
Decision Date:	**April 23, 2009**
Default Date:	**April 23, 2009**
Staff Assigned:	**Alexis G. Fedorjaczenko Steven W. Lazarus**

Project Description: Greenwich Hospital and Yale-New Haven Hospital propose to establish and operate a five year demonstration elective angioplasty program without onsite surgical backup at Greenwich Hospital, at an estimated total capital expenditure of $80,000.

Nature of Proceedings: On January 23, 2009, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from Greenwich Hospital and Yale-New Haven Hospital to establish and operate a five year demonstration elective angioplasty program without onsite surgical backup at Greenwich Hospital, at an estimated total capital

expenditure of $80,000. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Pursuant to Section 19a-638, C.G.S., a notice to the public concerning OHCA's receipt of the Applicants' Letter of Intent was published in the *New Haven Register* on July 31, 2008, and the *Greenwich Times* on August 8, 2008. OHCA received no responses from the public concerning the Applicants' proposal.

Pursuant to Section 19a-638, C.G.S., a public hearing regarding the CON application was held on February 24, 2009. On February 6, 2009, the Applicant was notified of the date, time, and place of the hearing. On February 10, 2009, a notice to the public announcing the hearing was published in *The Greenwich Times* and *New Haven Register*. Commissioner Cristine A. Vogel served as Presiding Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-638, C.G.S.

By petition dated February 19, 2009, The Stamford Hospital requested Party, or in the alternative, Intervenor status with full rights of cross-examination regarding the Applicants' CON application. The Presiding Officer denied the request of The Stamford Hospital for Party status and designated The Stamford Hospital as an Intervenor with full rights of participation.

The Presiding Officer heard testimony from the Applicants' witnesses and the Intervenor's witnesses in rendering this decision and considered the entire record of the proceeding.

OHCA's authority to review and approve, modify or deny the CON application is established by Section 19a-638, C.G.S. The provisions of this section as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

After Consideration of the entire record the following facts are found and conclusions of law are reached:

Clear Public Need
Impact of the Proposal on the Applicants' Current Utilization Statistics
Proposal's Contribution to the Quality of Health Care Delivery in the Region
Proposal's Contribution to the Accessibility of Health Care Delivery in the Region

1. It is found that Greenwich Hospital ("GH" or "Hospital") is a not-for-profit 174-bed acute care hospital located at 5 Perryridge Road in Greenwich, Connecticut, and is a member of the Yale-New Haven Health System ("YNHHS"). *(July 25, 2008, Letter of Intent)*

2. It is found that Yale-New Haven Hospital ("YNHH") is a not-for-profit 852-bed acute care hospital located at 20 York Street, New Haven, Connecticut, and is a member of YNHHS. *(November 21, 2008, Initial CON Application, page 237)*

3. It is found that as part of the Yale-New Haven Heart and Vascular Center ("YNHHVC"), GH currently provides diagnostic cardiac services including echocardiography, nuclear cardiac imaging, stress testing, cardiac CT angiography, and diagnostic cardiac catheterization. GH also provides interventional cardiac (primary angioplasty) services for patients that present on an emergency basis with ST-segment elevation MI or new onset left bundle branch block. *(July 25, 2008, Letter of Intent and November 21, 2008, Initial CON Application, pages 12-13)*

4. It is found that the primary (emergency) angioplasty for acute myocardial infarction ("PAMI") at GH received permanent status approval from OHCA on July 25, 2008, after completion of a 3-year demonstration project. *(July 25, 2008, Docket Number 08-30148-MDF)*

5. Angioplasty is historically a procedure in which a balloon tipped catheter is advanced to an artery narrowed from the buildup of cholesterol-laden plaque, but has been expanded to include other devices that serve as adjuncts to the balloon catheter, such as stents. Percutaneous coronary intervention ("PCI") also refers to this broader group of technologies. PCI for patients that present on an emergency basis with ST-segment elevation MI or new onset left bundle branch block is referred to as "primary" PCI. Other PCI procedures are referred to as "elective" PCI.

6. The Applicants are now proposing to establish and operate a five year demonstration elective angioplasty program without onsite surgical backup at GH. Elective angioplasty is the same procedure as primary angioplasty but is typically a scheduled procedure (within 72 hours) and is not an emergency.

7. The Applicants requested that its proposal be considered the sole demonstration project for elective angioplasty without cardiac surgery in Connecticut for 5 years. The Applicants assert that the Yale-New Haven Heart and Vascular Center, in collaboration with its satellites, will establish the quality program that will allow OHCA to determine if the demonstration project is successful before such services are permitted at other Connecticut hospitals. (*November 21, 2008, Initial CON Application, p. 10)*

8. The Applicants claim that the proposed 5 year demonstration project is a "very deliberate way to test the viability of providing safe, high quality elective angioplasty care without surgical backup through an infrastructure that extends the quality and sophistication of a leading academic medical center." (*November 21, 2008, Initial CON Application, p.10*)

9. The Applicants provided the following historical cardiac volumes for GH and YNHH for Fiscal Years ("FYs") 2005-2008:

Table 1a: Primary and Elective Angioplasty

	FY 2005	FY 2006	FY 2007	FY 2008
GH	22*	38	33	41
YNHH	2,657	2,457	2,268	2,387

Note: Data reported to PCR and GH data to GH Cardiac Registry Data
* GH PAMI began 2/28/05

Table 1b: Open Heart Surgery

	FY 2005	FY 2006	FY 2007	FY 2008
GH	--	--	--	--
YNHH	980	785	729	387*

* CHIME FY 2008 6 months

Table 1c: Cardiac Catheterization

	FY 2005	FY 2006	FY 2007	FY 2008
GH	209	290	260	302
YNHH	3,101	2,954	2,715	2,831

Note: Data as reported to PCR and GH data to GH Cardiac Registry Data
(November 21, 2008, Initial CON Application, page 21)

10. The Applicants asserted that there is a need for elective angioplasty at GH based upon several factors, including the strength of GH's PAMI program, the aging of the population, the disruption of care due to the lack of elective angioplasty services, and referring physicians' preference to send patients to hospitals with full cardiac services. *(January 23, 2009, Completeness Response, page 284)*

11. In support of their claim that there is a need for elective angioplasty at GH, the Applicants provided the following information regarding the number of patients who presented at the GH emergency department ("ED") with diagnoses of acute myocardial infarction, intermediate coronary syndrome, ischemia, angina, and coronary atherosclerosis and could be considered "PCI-Eligible":

Table 2: "PCI-Eligible" GH ED Admissions

	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009*
ED Admissions	99	167	151	212	223	228	228	252

Note: Applicants sourced GH internal data
* Annualized based on first quarter
(January 23, 2009, Completeness Response, page 285)

12. The Applicants testified that the above-referenced "PCI-Eligible" GH ED admissions are not patients who had a PCI or who would absolutely have a PCI but rather "it is meant to represent the types of diagnoses of patients who present to Greenwich Hospital, a portion of which may need a PCI." *(February 24, 2009, Public Hearing Testimony of Margaret Martino, Program Director for Cardiology and Medicine, Greenwich Hospital)*

13. The Applicants testified that they do not know the exact disposition of the above-referenced "PCI-Eligible" GH ED admissions. *(February 24, 2009, Public Hearing Testimony of Margaret Martino, Program Director for Cardiology and Medicine, Greenwich Hospital)*

14. Christopher J. Howes, M.D., Medical Director, Interventional Cardiology & PAMI Program, Greenwich Hospital, testified on behalf of the Applicants, that it would even be a stretch to say it may be likely that the "PCI-Eligible" ED Admissions would result in a PCI. *(February 24, 2009, Public Hearing Testimony of Christopher J. Howes, M.D., Medical Director, Interventional Cardiology & PAMI Program, Greenwich Hospital; Assistant Professor, Yale University School of Medicine)*

15. Dr. Collins, on behalf of The Stamford Hospital ("TSH"), testified that the Applicants' assertion that GH's ED admissions of patients with acute myocardial infarction, intermediate coronary syndrome, ischemia, angina and coronary atherosclerosis demonstrate a patient population eligible for PCI is an extreme generalization. These diagnoses alone do not automatically translate to PCI eligibility. *(February 19, 2009, Pre-file Testimony, Michael Collins, Associate Director of the Cardiac Catheterization lab at New York Presbyterian-Columbia University Medical Center, page 6)*

16. It is found that the Applicants failed to present any credible evidence that the so-called "PCI-Eligible" GH ED Admissions would actually result in PCI cases performed at GH. Accordingly, OHCA does not find that this information demonstrates a need for elective angioplasty at GH.

17. The Applicants also provided the following number of PAMI cases, number of PCI transfers (for patients that had a cardiac catheterization at GH), and number of PCI referrals during the past four PAMI program years at GH to show that there is a need for elective angioplasty at GH. The data is from the GH Department of Cardiology Cardiac Catheterization Database.

Table 3: PAMI Cases, Transfers, and Referrals at GH

	PAMI Program Year 1 (2/28/05-2/27/06)	**PAMI Program Year 2** (2/28/06-2/27/07)	**PAMI Program Year 3** (2/28/07-2/27/08)	**PAMI Program Year 4** *Year-To-Date* (2/28/08-12/31/08)
PAMI	33	40	39	37
PCI Transfers*	31	49	40	52
PCI Referrals**	N/A	N/A	4	7

Note: Applicants sourced GH Department of Cardiology Cardiac Catheterization Database
*PCI transfers are patients who had a cardiac catheterization at GH and were transferred to another facility for PCI
** A referral is defined as patients discharged from GH and scheduled for a PCI at an alternate facility *(January 23, 2009, Completeness Response, page 285)*

18. It is found that the above-referenced table demonstrates the actual number of patients who were either transferred or referred from GH to another facility for elective PCI.

19. GH contends that the service area for the proposal includes the following CT and NY towns:

Table 4: Service Area Towns, GH

	Connecticut	New York
Primary Service Area ("PSA")	Darien	Harrison
	Greenwich	Larchmont
	New Canaan	Mamaroneck
	Stamford	Port Chester
		Rye
Secondary Service Area ("SSA")	Norwalk	Armonk
	Weston	Bedford
	Westport	Bedford Hills
	Wilton	Hartsdale
		Katonah
		Mount Kisco
		Mount Vernon
		New Rochelle
		Pound Ridge
		Purchase
		Scarsdale
		South Salem
		White Plains

(November 21, 2008, Initial CON Application, page 77 and January 23, 2009, Completeness Response, page 284)

20. The Applicants contend that approximately 40% of Greenwich Hospital inpatients come from nearby New York towns. (*January 23, 2009, Completeness Response, pages 284*)

21. GH includes towns in Westchester County, New York in its service area. Connecticut General Statutes §§ 19a-634 and 19a-637, however, specifically mandate that OHCA consider the availability, scope and need for services for the residents of Connecticut. Therefore, OHCA does not consider out of state volume in its evaluation of need for the proposed services.

22. The Applicants contend that the program's volume would come predominantly from Greenwich and its immediate environs and is not anticipated to impact other providers. *(November 21, 2008, Initial CON Application, page 16)*

23. It is found that the following table represents OHCA's Market Share Analysis of the GH service area based upon discharge data submitted pursuant to General Statutes § 19a-654 by Connecticut hospitals to OHCA's Acute Care Hospital Inpatient Discharge Database ("HIDD") for FY 2008:

Table 5: GH Service Area Discharge Data & Market Share

	Total Town Discharges	Total GH Discharges	% of Hospital Total Discharges	Share of Town
Greenwich	4,819	3,948	37%	82%
Darien	1,211	196	2%	16%
New Canaan	1,332	131	1%	10%
Stamford	11,119	761	7%	7%

(State of Connecticut, OHCA Acute Care Hospital Inpatient Discharge Database)

24. According to OHCA's HIDD, of the 4,819 patients that were discharged from a CT hospital and reside in Greenwich, 82% utilized GH and accounted for 37% of GH's total discharge volume. Therefore, OHCA finds that GH primarily serves the residents of the town of Greenwich.

25. It is found that The Stamford Hospital, which began providing elective angioplasty with surgical backup in October 2008, is the only provider of the proposed service in the Applicants' primary service area and secondary service area. *(November 21, 2008, Initial CON Application, page 16)*

26. Dr. John F. Rodis, on behalf of TSH, testified that GH is only 6 miles away from TSH and that the full impact of TSH's new elective angioplasty program on the region has not yet been determined and that this should be done before OHCA approves any new programs in the region. *(February 19, 2009, Pre-file Testimony, John F. Rodis Senior Vice President of Medical Affairs and Chief Medical Officer for The Stamford Hospital, pages 2-4)*

27. It is found that as of February 17, 2009, TSH had performed 94 PCIs, which translates to over 286 PCIs on an annualized basis. *(February 19, 2009, Pre-file Testimony, John F. Rodis Senior Vice President of Medical Affairs and Chief Medical Officer for The Stamford Hospital, pages 2-4)*

28. It is found that the following table from OHCA's HIDD shows the total number of PCIs in the GH service area towns, the hospitals utilized for those services and total percentage of PCIs from the GH service area towns for each hospital:

Table 6: PCI Providers in Greenwich Hospital Service Area, FFY 2008

Greenwich Hospital Service Area Towns	Bridgeport	Yale	Saint Raphael	Greenwich	Stamford	Saint Vincent's	Danbury	Total
Darien	<6	<6			<6	10		19
Greenwich	<6	42		17	<6	<6		68
New Canaan	7	<6				26		34
Norwalk	27	6		<6	<6	191		228
Stamford	29	10		<6	29	94		166
Weston	<6					8	<6	11
Westport	21	<6	<6			41	<6	66
Wilton	<6					21		25
GH Service Area Total	97	64	<6	23	34	396	<6	617
% GH Service Area	16%	10%	0%	4%	6%	64%	0%	100%

*Unduplicated discharge count based on ICD-9-CM primary and secondary procedure codes: 0.66 (replaced 36.01, 36.02 & 36.05), 36.01, 36.02, 36.03, 36.05, 36.06 and 36.07
NB: Hospital service area towns were provided by Greenwich Hospital in the application.
Cell values less than six are replaced with "<6" to protect patient confidentiality
(State of Connecticut, OHCA Acute Care Hospital Inpatient Discharge Database)

29. The Applicants provided the following table with respect to the actual and annualized volume of angioplasty procedures by GH proposed service area:

Table 7: Total Primary and Elective PCI Actual/Annualized Procedures by Service Area

	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008*
CT PSA	338	365	293	345	383	307	306
CT SSA	275	235	275	296	347	328	304
State of CT	7,535	8,150	7,855	7,401	7,860	7,337	7,690
NY SA	746	717	737	799	938	778	785

** Annualized*
Note: The Applicants sourced the FY 2002-2005 CT PSA & SSA and all of NY SA is CHA CHIME and NY data is SPARCS
(January 23, 2009, Completeness Response, page 298)

30. The Applicants claim that in Connecticut, angioplasty volume is increasing and the most recent data from ChimeData[1] shows that it is up 6.1% statewide. *(February 24, 2009, Public Hearing Testimony of Marna Borgstrom, President/Chief Executive Officer of Yale New-Haven Health System and Yale New-Haven Hospital)*

[1] The Connecticut Hospital Association offers data collection and reporting services to its acute care hospital members through its ChimeData program. In addition, ChimeData is used to help hospitals meet regulatory reporting requirements by submitting inpatient data to the Connecticut Office of Health Care Access.

31. It is found that the following table represents the total primary and elective PCI actual volume by GH proposed service area from OHCA's HIDD:

Table 8: GH* & CT PCI Volume (OHCA Database)

	FY 2006	FY 2007	FY 2008**
GH CT PSA	383	307	287
GH CT SSA	350	327	330
State of CT	7,871	7,348	7,221

Note:
* Unduplicated discharge count based on ICD-9-CM primary and secondary procedure codes: 0.66, 36.01, 36.02, 36.03, 36.04, 36.05, 36.06, and 36.07.
**Excludes ICD-9-CM procedure code 37.61.
Service area town utilized are the same as provided by GH in this CON Application.
(State of Connecticut, OHCA Acute Care Hospital Inpatient Discharge Database)

32. Based upon the above-referenced data from OHCA's HIDD for the full year of actual FY 2008, it is found that PCI volume has declined statewide and has also declined in the GH proposed primary service area.

33. The Applicants contend that the following elective angioplasty projections will be realized for the first three years of the proposal:

Table 9: Proposed Elective Angioplasty Projections by GH Service areas

	Current Year	Year 1	Year 2	Year 3
GH CT PSA	20	30	53	85
GH CT SSA	4	6	6	10
GH NY	16	84	90	105
Total	**40**	**120**	**150**	**200**

(January 23, 2009, Completeness Response, page 298)

34. The Applicants testified that the proposal's projections do not take into account the percentage of patients who might not fulfill the recommended criteria for angioplasty without surgical backup. *(February 24, 2009, Public Hearing Testimony of Henry Cabin, M.D., F.A.C.C., Medical Director of the Yale-NewHaven Heart Center; Associate Section Chief of Cardiovascular Medicine, Yale-New Haven Hospital)*

35. The Applicants testified that although they could not identify a specific percentage of patients who would still need to be transferred to another hospital with surgical backup, such as YNHH, the number would probably be less than 20%. *(February 24, 2009, Public Hearing Testimony of Christopher J. Howes, M.D., Medical Director, Interventional Cardiology & PAMI Program, Greenwich Hospital; Assistant Professor, Yale University School of Medicine)*

36. The Applicants contend that they have been experiencing significant volume growth from New York towns over the past several years and stated that the main volume growth of the PCI program will come from GH's NY service area towns due to

increased referrals and patient preference for GH from bordering New York towns versus additional travel to Westchester Medical Center or New York City. *(November 21, 2008, Initial CON Application, pages 120-1 and January 23, 2009, Completeness Response, pages 287-8)*

37. Dr. John F. Rodis, testified that the Applicants have offered no data to establish any need on the part of New York residents for expanded elective angioplasty services. *(February 19, 2009, Pre-file Testimony, John F. Rodis Senior Vice President of Medical Affairs and Chief Medical Office for The Stamford Hospital , page 9)*

38. Based upon the volume projections provided by the Applicants, above in Finding of Fact 33, it appears that the Applicants expect the majority of the program's volume to originate from its NY service area at the following percentages: 70% in Year 1, 60% in Year 2 and 53% in Year 3.

39. It is found that the Applicants' volume projections are primarily based upon volume originating from NY despite the fact the OHCA does not consider out of state volumes in its evaluation of need for a proposed service. (*See Finding of Fact 21*)

40. It is found that the 2005 updated ACC/AHA/SCAI guidelines state: Class III. Elective PCI should not be performed at institutions that do not provide on-site cardiac surgery. The guidelines further state: "Elective PCI should not be performed at institutions that do not provide on-site cardiac surgery. (Level of Evidence: C) *Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program (18–28). A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate on-site availability of cardiac surgical support but cannot be managed effectively by urgent transfer. Wennberg et al. found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery (29). These recommendations may be subject to revision as clinical data and experience increase." *(Smith SC Jr,et al. ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention).* Circulation, 2006 Jan 3;113(1):156-75.)

41. Henry S. Cabin, M.D., F.A.C.C., Medical Director of the Yale-New Haven Heart Center, testified on behalf of the Applicants that he is unaware of any study that said it is safer to perform elective PCI without onsite surgical backup than to perform elective PCI with onsite surgical backup. *(February 24, 2009, Public Hearing Testimony of Henry Cabin, M.D., F.A.C.C., Medical Director of the Yale-NewHaven Heart Center; Associate Section Chief of Cardiovascular Medicine, Yale-New Haven Hospital)*

42. Dr. Cabin also testified that there are no new guidelines and it is not clear when new guidelines would come out because there is still so much controversy regarding this issue. *(February 24, 2009, Public Hearing Testimony of Henry Cabin, M.D., F.A.C.C., Medical Director of the Yale-NewHaven Heart Center; Associate Section Chief of Cardiovascular Medicine, Yale-New Haven Hospital)*

43. Similarly, Dr. Collins testified that performing elective PCI without onsite surgical backup is a controversial issue and "no one is claiming it is safer to do elective PCI without surgical standby available." *(February 24, 2009, Public Hearing Testimony of Michael Collins, M.D., F.A.C.C., Associate Director of the Cardiac Catheterization Lab at New York Presbyterian-Columbia University Medical Center)*

44. Dr. Collins also testified that elective PCI without on-site cardiac surgery remains a procedure that the current Guidelines recommend not be performed, as the *2007 Focused Update of the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention* did not modify or change the recommendation in any way. *(February 19, 2009, Pre-file Testimony, Michael Collins, Associate Director of the Cardiac Catheterization lab at New York Presbyterian-Columbia University Medical Center, page 5)*

45. Although the Applicants concede that elective angioplasty without onsite surgery is a highly debated issue, they also testified that it remains an issue that some states are still studying either through demonstration projects or outright approval. *(February 24, 2009, Public Hearing Testimony of Margaret Martino, Program Director for Cardiology and Medicine, Greenwich Hospital)*

46. The Applicants testified that the New York State Department of Public Health, Cardiac Service Program has authorized seven hospitals to provide elective angioplasty without onsite surgical backup and is in the process of writing program regulations. *(February 24, 2009, Public Hearing Testimony of Andre Spitzer, Planner, Yale-New Haven Hospital)*

47. The Applicants submitted a late file regarding New York's Demonstration Program, confirming that seven hospitals are currently participating in the Elective PCI Demonstration Project. *(Applicant's Late File Attachment 1 New York Demonstration Program)*

48. Additionally, the Applicants submitted the "Guidelines for Evaluating the Feasibility of Elective PCI in Facilities with no SOS, Endorsed by the NYS Cardiac Advisory Committee, May, 2006." *(Applicant's Late File Attachment 1 New York Demonstration Program)*

49. The New York State Guidelines have very specific review criteria, including, among other things, facility minimum volume projections of 200 PCI cases within 1 year of approval and 400 PCI cases by the end of the third year of operation. *(Applicant's Late File Attachment 1 New York Demonstration Program)*

50. According to the 2007 SCAI Consensus Document, "[f]acilities performing both primary and elective PCI without on-site surgery currently exists in 28 states. In some states, this situation is allowed only through a controlled demonstration project run by the state's Department of Public Health. A large . . . randomized trial of elective PCI without on-site surgery (The Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study) is currently enrolling patients and includes facilities in several states where elective PCI without on-site backup has been prohibited." *(Dehmer, Gregory J, et al., " The Current Status and Future Direction of PCI Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular*

Angiography and Interventions, "Catheterization and Cardiovascular Interventions, March 2007, volume 69, issue 4)

51. It is found that the 2007 SCAI Consensus document recommends that: "facilities performing both primary and elective procedures without on-site surgery perform a minimum of 200 PCI/year. Programs with <200 PCI/year should be reviewed on an individual basis. They should remain open only if they are in geographically isolated or underserved areas and their performance metrics are equivalent to accepted benchmarks. *(Dehmer, Gregory J, et al., " The Current Status and Future Direction of PCI Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions, "Catheterization and Cardiovascular Interventions, March 2007, volume 69, issue 4)*

52. It is found that the nationally recognized guidelines do not support elective PCI without onsite surgical backup and although some states are conducting research in the area, currently Connecticut has not established such protocols.

53. It is also found that although OHCA is not bound to the ACC/AHA/SCAI guidelines, these guidelines are instructive.

54. It is found that the Applicants' projections do not reach 200 until year three (3) and that they have not demonstrated they are located in a geographically isolated or underserved area.

Financial Feasibility and Cost Effectiveness of the Proposal and its Impact on the Applicants' Rates and Financial Condition; Impact of the Proposal on the Interests of Consumers of Health Care Services and the Payers for Such Services and Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

55. The Applicants contend that the project's total capital expenditure of $80,000 is for the purchase of medical equipment such as IVUs and pressure wires. *(November 21, 2008, Initial CON Application, pages 30 & 34)*

56. GH's projected incremental revenue from operations, total operating expense and gain from operations associated with the CON proposal are as follows:

Table 10: Financial Projections Incremental to the Project

Description	FY 2010	FY 2011	FY 2012
Incremental Revenue from Operations	$2,054	$2,911	$4,311
Incremental Total Operating Expense	$1,289	$1,848	$2,741
Incremental Gain from Operations	**$765**	**$1,063**	**$1,570**

Note: figures are in thousands.
(November 21, 2008, Initial CON Application, pages 269-70)

57. It is found that the Applicants indicated that there are no projected incremental revenue from operations, total operating expense or gain from operations associated with the CON proposal for YNHH. *(November 21, 2008, Initial CON Application, pages 271-2)*

58. The Applicants contend that the three (3) year projected payer mix for the proposed PCI program is as follows:

Table 11: Three-Year Projected Payer Mix, Program Only

Description	Year 1	Year 2	Year 3
Medicare	27.96%	30.30%	29.69%
Medicaid	9.68%	9.09%	9.38%
CHAMPUS and TriCare	0.00%	0.00%	0.00%
Total Government	**37.63%**	**39.39%**	**39.06%**
Commercial Insurers*	52.69%	51.52%	52.08%
Self Pay	9.68%	9.09%	8.85%
Workers Compensation	0.00%	0.00%	0.00%
Total Non-Government	**62.37%**	**60.61%**	**60.94%**
Total Payer Mix	**100.00%**	**100.00%**	**100.00%**

* Includes managed care activity.
Note: Based on information provided by the Applicants in Financial Attachment II
(November 21, 2008, Initial CON Application, pages 275-77)

59. Although the Applicants did not provide a basis for the payer mix distribution as calculated in the Financial Attachment II (pages 275-277), OHCA finds the payer mix assumptions reasonable.

60. The Applicants contend to the following information in Financial Attachment II for FYs 2010-2012:

Table 12: Projected Rates, Net Revenues and PCI Cases

	FY 2010	FY 2011	FY 2012
Annual Rate for proposed PCI per case	$85,631	$90,212	$96,911
Units of service (PCI)	93	132	192
Projected Net Revenue	$2,054,906	$2,910,755	$4,311,421

(November 21, 2008, Initial CON Application, pages 275-277)

61. There is no State Health Plan in existence at this time. *(November 21, 2008, Initial CON Application, page 8)*

62. The Applicants have adduced evidence that the proposal is consistent with their long-range plans. *(November 21, 2008, Initial CON Application, page 8)*

63. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, and applications of new technology. *(November 21, 2008, Initial CON Application, page 28)*

64. The proposal will not result in any change to the Applicants' teaching and research responsibilities. *(November 21, 2008, Initial CON Application, page 28)*

65. There are no characteristics of the Applicants' patient/physician mix that make the proposal unique. *(November 21, 2008, Initial CON Application, page 28)*

66. The Applicants contend that the rates are sufficient to cover the proposed capital expenditure and operating costs associated with the proposal. *(August 13, 2008, Initial CON Application, pages 274-80)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for Certificate of Need ("CON") proposals on a case-by-case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

Greenwich Hospital ("GH") is a 174-bed acute care hospital located at 5 Perryridge Road in Greenwich and Yale-New Haven Hospital ("YNHH") is an 852-bed acute care hospital located at 20 York Street in New Haven. GH and YNHH (collectively known as "Applicants") are proposing to establish and operate a five year demonstration elective angioplasty program without onsite surgical backup located at GH.

Currently, GH provides cardiac catheterization and primary (emergency) angioplasty services. GH performed 290, 260 and 302 cardiac catheterizations and 38, 33 and 41 primary angioplasties during fiscal years (FYs) 2006-2008, respectively. Recognizing the current debate over the safety and quality of elective PCI without on-site surgical backup, the Applicants propose that GH should be the first and only hospital in Connecticut to offer elective angioplasty ("PCI") without onsite surgical backup under the guidance of a five year demonstration project to research concerns around quality and safety. It is undisputed that the current nationally recognized guidelines do not support such programs. (Findings of Fact 40-44.) Although some states are allowing some hospitals to provide elective PCI without onsite surgical backup through demonstration projects or through the Atlantic CPORT Study (Findings of Fact 45-50), Connecticut does not have such a program nor are any of its hospitals participating in such a program. Furthermore, at this time, OHCA does not find that the proposed demonstration project is necessary to improve the quality or accessibility of cardiovascular treatment in Connecticut.

Even assuming OHCA were willing to approve the proposed demonstration project to evaluate the efficacy and safety of an elective angioplasty program without onsite surgical backup, it appears that other states require hospitals participating in such a program to meet or exceed minimum volumes as recommended by the 2007 SCAI Consensus document. (Findings of Fact 49 & 51) For example, New York requires that hospitals participating in its program achieve at least 200 PCI cases within 1 year of approval and at least 400 PCI cases at the end of the third year of operation. (Finding of Fact 49) Although GH contends that it will perform the minimum recommended standard volume for PCI of 200 annually; OHCA notes that GH will not meet the minimum recommended PCI volume in either of the first two years of the proposal (Finding of Fact 33 & 54) The above-referenced 2007 SCAI consensus document recommends that programs performing <200 elective PCIs annually without onsite surgical backup should be reviewed on an individual basis and remain open only if they are in geographically isolated or underserved areas and their performance metrics are equivalent to acceptable benchmarks. (Finding of Fact 51) Although OHCA is not bound by the ACC/AHA/SCAI guidelines, OHCA finds that these guidelines are instructive on this issue. (Finding of Fact 53) In addition to GH's relatively low volume projections for the proposed

program, data from OHCA's Hospital Inpatient Discharge Database ("HIDD") (Finding of Fact 31) indicates a decline in PCI volume in Greenwich Hospital's proposed service area and also statewide for the past two years. Based upon the Applicants relatively low volume projections as well as the declining statewide PCI volumes, OHCA is unable to conclude that the proposed demonstration project would improve the quality and accessibility of care provided in the Greenwich area, particularly in light of the availability of full service cardiac programs in Fairfield County. (Finding of Fact 28)

The Stamford Hospital ("TSH"), which is located approximately six miles from GH, began operation of its full service cardiac program including elective PCI in October 2008 and based on current activity, is projected to perform 286 PCIs in the first year. (Findings of Fact 25-27) In addition to TSH, there are several nearby hospitals that cardiac patients may elect or be transported to depending upon the urgency and the clinical presentation. (Finding of Fact 28) Although the Applicants attempt to demonstrate a need for the proposed service by asserting that the majority of its program volume would originate from New York (Findings of Fact 36-39), OHCA does not consider out of state volume in its evaluation of need for a proposed service. The Applicants have based over 50% of their volume projections for this service on out of state volume from New York. (Finding of Fact 38) The only credible evidence the Applicants have provided in support of their volume projections are the actual number of patients who were either transferred or referred from GH to another facility for PCI in during the past four years of its PAMI program. (Findings of Fact 17-18) The Applicants attempted to show additional volume by providing so-called "PCI-Eligible" GH ED admissions; however, OHCA found that this information was not credible and therefore, did not demonstrate a need for elective angioplasty at GH. Furthermore, the Applicants concede that their volume projections for the proposal did not take into account the percentage of patients who might not fulfill the recommended criteria for angioplasty without surgical backup. (Finding of Fact 34) Therefore, OHCA is unable to definitively conclude that there is a need for such a program particularly in light of the fact that the majority of the projected volume for the proposal will originate from New York, the lack of credible evidence substantiating the projected volumes and the availability of elective angioplasty at nearby hospitals with full service cardiac programs. Accordingly, OHCA concludes that the Applicants have failed to demonstrate that a clear public need exists for an elective angioplasty program without onsite surgical backup at GH.

Based upon the lack of evidence demonstrating that the Applicant's proposed demonstration project would contribute positively to the quality and accessibility of health care delivery in the region as well as the lack of a clear public need for the proposal, OHCA is unable to conclude that the Applicants' financial projections and volumes upon which they are based are reasonable and achievable, or that the project is financially feasible.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Greenwich Hospital and Yale-New Haven Hospital for the establishment and operation of a five year demonstration elective angioplasty program without onsite surgical backup at Greenwich Hospital, at a proposed total capital expenditure of $80,000, is hereby **DENIED**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the

4-23-09
Date

Cristine A. Vogel
Commissioner

CAV:agf/swl