



STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

January 31, 2013

IN THE MATTER OF:

An Application for a Certificate of Need
filed pursuant to General Statutes § 19a-638
(a) (1) by:

**Greenwich Hospital and
Yale-New Haven Hospital**

Notice of Final Decision
Office of Health Care Access
Docket Number: 12-31748-CON

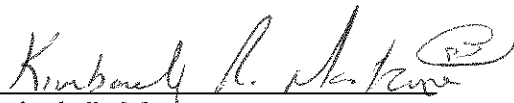
**Establish and Operate an Elective
Angioplasty Program Without Onsite
Surgical Backup at Greenwich Hospital**

To: Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510

Dear Attorney Groves:

In accordance with the Connecticut General Statutes Section 4-179, the Proposed Final Decision dated November 20, 2012, by Hearing Officer Joanne Yandow, Esq., is hereby adopted as the final decision of the Deputy Commissioner of Department of Public Health in this matter. A copy of the Proposed Final Decision is attached hereto and incorporated herein.

Sincerely,



Kimberly R. Martone,
Director of Operations

KRM: swl

cc: Marianne Horn, Esq., Hearing Officer, DPH

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

In Re: Greenwich Hospital and Yale-New Haven Hospital
Docket Number: 12-31748-CON

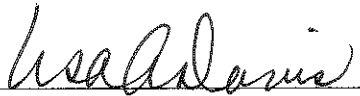
FINAL DECISION

On November 20, 2012, a Proposed Final Decision was issued in the above matter pursuant to Section 4-179 of the Connecticut General Statutes.

In accordance with Connecticut General Statutes Section 4-179, the attached Proposed Final Decision dated November 20, 2012 by Hearing Officer Joanne Yandow, Esq., is hereby adopted as the final decision of the Deputy Commissioner of the Department of Public Health in this matter. A copy of the Proposed Final Decision is attached hereto and incorporated herein.

WHEREFORE, it is the final decision of the Deputy Commissioner that the application of Greenwich Hospital and Yale-New Haven Hospital, to establish and operate an elective angioplasty program without onsite surgical backup at Greenwich Hospital, is hereby denied.

1/31/13
Date


Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner



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Office of Health Care Access Certificate of Need Application

Proposed Final Decision

Applicant: Greenwich Hospital and
Yale-New Haven Hospital

Docket Number: 12-31748-CON

Project Title: Establish and Operate an Elective Angioplasty
Program without Onsite Surgical Backup at Greenwich
Hospital

Project Description: Greenwich Hospital and Yale-New Haven Hospital propose to establish and operate an elective angioplasty program without onsite surgical backup at Greenwich Hospital, with no associated capital expenditure.

Nature of Proceedings: On June 20, 2012, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from Greenwich Hospital and Yale-New Haven Hospital to establish an elective angioplasty program without onsite backup at Greenwich Hospital, with no associated capital expenditure. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("General Statutes").

Pursuant to General Statutes § 19a-638, a public hearing regarding the CON application was held on July 17, 2012. On July 2, 2012, the Applicant was notified of the date, time, and place of the hearing. On July 3, 2012, a notice to the public announcing the hearing was published in *The Greenwich Times*. Attorney Joanne V. Yandow served as Hearing Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the General Statutes) and General Statutes § 19a-638.

By petition dated July 12, 2012, The Stamford Hospital requested Party or, in the alternative, Intervenor status with full rights of cross-examination regarding the Applicants' CON application. The Hearing Officer denied the request of The Stamford Hospital for Party status and designated The Stamford Hospital as an Intervenor with limited rights of participation.

The Hearing Officer heard testimony from the Applicants' witnesses and the Intervenor's witnesses and, in rendering this decision, considered the entire record of the proceeding. The public hearing record was closed on September 6, 2012.

OHCA's authority to review and approve, modify, or deny the CON application is established by General Statutes § 19a-638. The provisions of this section, as well as the principles and guidelines set forth in General Statutes § 19a-639, were fully considered by OHCA in its review.

Findings of Fact

1. Greenwich Hospital is a not-for-profit 174-bed acute care hospital located at 5 Perryridge Road in Greenwich, Connecticut. Exhibit A, p. 573 (CON Application).
2. Yale-New Haven Hospital is a not-for-profit, acute care hospital located at 20 York Street, New Haven, Connecticut. Exhibit A, p. 575 (CON Application).
3. The Yale-New Haven Heart and Vascular Center provides elective and emergency ("primary") angioplasty at Yale-New Haven Hospital and has established satellite primary angioplasty programs at Greenwich Hospital and Lawrence & Memorial Hospital in New London, Connecticut. Exhibit H, pp. 629&632 (prefiled testimony of Marna Borgstrom, President and CEO of Yale-New Haven Health System and CEO of Yale New Haven Hospital); OHCA CON Final Decision, DN: 03-30148.
4. 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 a "primary" PCI. Other PCI procedures are referred to as "elective" PCI. *See*, OHCA CON Final Decision, DN: 08-31210.
5. As part of Yale-New Haven Heart and Vascular Center, Greenwich Hospital currently provides diagnostic cardiac services including echocardiography, nuclear cardiac imaging, stress testing, cardiac CT angiography, and diagnostic cardiac catheterization. Greenwich Hospital also provides PCI angioplasty services for patients that present on an emergency basis with artery blockage in the heart. Exhibit A, pp. 22-23 (CON Application).
6. The primary angioplasty program at Greenwich Hospital received permanent status approval from OHCA on July 25, 2008, after completion of a 3-year demonstration project. Exhibit A, p. 22 (CON Application); OHCA CON Final Decision, DN: 03-30148.
7. Elective angioplasty is the same procedure as primary angioplasty but is typically a scheduled procedure (within 72 hours) and is not an emergency. *See*, OHCA CON Final Decision, DN: 08-31210.

8. The Applicants are proposing to establish an elective angioplasty program at Greenwich Hospital without an on-site open heart surgery program. Exhibit A, p. 14 (CON Application).
9. The Applicants define the population to be served through this proposal as the residents of the towns that comprise 85% of Greenwich Hospital's inpatient volume. The Applicants claim that the proposed service area ("PSA") is as follows:

Table I: Greenwich Hospital's PSA for Elective PCI

State	Towns
Connecticut	Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston, Westport and Wilton
New York	Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneek, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Pound Ridge, Purchase, Rye Scarsdale, South Salem, West Harrison and White Plains

Exhibit A, p. 24 (CON Application).

10. The Stamford Hospital ("Stamford Hospital"), the Intervenor in this matter, performs cardiovascular services, including primary and elective PCIs. *See*, OHCA CON Final Decision, DN: 04-30374.
11. The Applicants claim that based on the 2011 inpatient cardiovascular discharge volume by patients' towns of origin for Stamford Hospital and Greenwich Hospital, cardiovascular patients at Greenwich Hospital are the low volume communities for Stamford Hospital. Specifically, the communities of Greenwich, Port Chester and Rye comprise 80% of Greenwich Hospital's cardiovascular patient population but only 4.6% of Stamford Hospital's cardiovascular patient population. Additionally, patients who live in the city of Stamford and the town of Darien comprise 88% of Stamford Hospital's cardiovascular patient volume but only comprise 7% of Greenwich Hospital's cardiovascular patients. Exhibit H, pp. 668-669 (prefiled testimony of Christopher Howes, MD, Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital).

12. In 2010, OHCA issued a decision denying Greenwich Hospital's first proposal to establish and operate elective angioplasty program without on-site open heart surgery. The proposal was denied because the projected volume included New York patients, there was insufficient evidence to support the projected volumes, and there was an existing provider of elective PCI and full service cardiac program in the service area (Stamford Hospital). CON Final Decision 08-31210-CON.
13. In or about January 2012, White Plains Hospital in White Plains, New York began offering elective angioplasty service. . Exhibit I, p. 49-50 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).
14. Stamford Hospital and White Plains Hospital are currently providing elective angioplasty procedures in Greenwich Hospital's claimed PSA. Exhibit A, p. 28 (CON Application).
15. White Plains Hospital states it services most of the Westchester County towns identified by the Applicants as towns in Greenwich Hospital's PSA. Exhibit I, page, 49 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).
16. The Applicants assert that Greenwich Hospital is already performing angioplasty on more acutely ill patients through its primary angioplasty program and the staff and physicians are well prepared to perform elective angioplasty for less acute patients. Exhibit A, p. 14 (CON Application).
17. The Medical Director of the cardiac services program at Greenwich Hospital is appointed by Yale University School of Medicine, Department of Cardiology and is a member of the Yale School of Medicine's interventional cardiology faculty. Exhibit A, p. 14 (CON Application).
18. The Applicants claim that the previous OHCA approval for the primary PCI demonstrated clear public need for emergency angioplasty services at Greenwich Hospital and that the current proposal expands upon that approval to demonstrate that the same population, from which Greenwich Hospital's primary angioplasty patients originate, also have a clear need for access to their provider of choice for high quality elective angioplasty services. Exhibit A, p. 15 (CON Application).
19. The Applicants claim that the clear public need for this proposal is supported by the following three key factors:
 - a. Local access to elective angioplasty care at Greenwich Hospital is needed and appropriate;
 - b. Greenwich Hospital must address the cost-effectiveness of angioplasty services; and
 - c. The proposed program will improve the quality of elective angioplasty services provided to Greenwich Hospital's PSA patients.
Exhibit A, p. 15 (CON Application).

20. The Applicants assert that significant stress and strain are placed on Greenwich Hospital patients and their families when they receive either a diagnostic catheterization or an emergency angioplasty and then must undergo an elective angioplasty at another facility. Exhibit H, p. 671 (prefiled testimony of Christopher Howes, MD, Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital).
21. In November 2011, the American College of Cardiology/American Heart Association/The Society for Cardiovascular Angiography and Interventions ("ACC/AHA/SCAI") updated their guidelines regarding PCI without on-site surgical backup. These guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of specific diseases or condition. Exhibit A, pp. 139-239 (CON Application).
22. The Applicants claim that an elective PCI program at Greenwich Hospital would fall within the ACC/AHA/SCAI updated guidelines. Exhibit H, pp. 635-636 (prefiled testimony of Henry Cabin, MD, Clinical Chief of Cardiology at Yale School of Medicine and Medical Director of Yale-New Haven Heart and Vascular Center).
23. The ACC/AHA/SCAI updated guidelines recommend, in part, that:
elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.
Exhibit A, p. 164 (CON Application).
24. The ACC/AHA/SCAI guidelines also recommend, in part, that:
[i]t is only appropriate to consider initiation of a PCI program without on-site backup if the program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.
Exhibit A, p. 164 (CON Application).
25. It is found that although OHCA is not bound to the ACC/AHA/SCAI guidelines, these guidelines are instructive. *See*, CON Final Decision 08-31210-CON.
26. The Applicants claim that angioplasty has become a fairly routine procedure, often performed in an outpatient setting at much lower risk than used to exist. Exhibit H, p. 632. (prefiled testimony of Marna Borgstrom, President and CEO of Yale New Haven Health System and CBO of Yale-New Haven Hospital).
27. The Applicants claim that this proposal eliminates the need for two invasive procedures, diagnostic cardiac catheterization and elective angioplasty, which adds hospital costs, clinical risk and expensive medical transportation costs. Exhibit H, pp.

632 and 671 (prefiled testimonies of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale New Haven Hospital, and Christopher Howes, MD, Chief of Cardiology and Medical Director of the angioplasty program at Greenwich Hospital).

28. The Applicants assert that Yale School of Medicine cardiovascular physicians have been actively involved in the primary angioplasty program at Greenwich Hospital since its inception and will continue to provide clinical oversight, direct patient care, and staff and physician education at the proposed program. Exhibit H, p. 632 (prefiled testimony of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale New Haven Hospital).
29. The Applicants state that Greenwich Hospital participates in the National Cardiovascular Data Registry NCDR-CathPCI Registry. Exhibit A, p. 36 (CON Application).
30. According to the Applicants, since Fiscal Year ("FY") 2008, 272 patients presented at Greenwich Hospital for elective angioplasty service. A total of 246 of the 272 patients were transferred to other providers for elective PCI. The following table illustrates the total of transfers by provider:

Table II: Historical Greenwich Hospital Elective PCI Transfers

FY	Yale	Westchester Medical Center	Cornell	Columbia	Stamford	West Haven VA	Total Transfers
2008	44	1	0	0	0	0	45
2009	71	0	1	1	1	0	74
2010	51	0	2	0	1	0	54
2011	53	0	2	1	0	1	57
2012*	16	0	0	0	0	0	16
Totals	235	1	5	2	2	1	246

*Number of transfers between 10/1/11 and 12/31/11

Note: The remaining 26 patients were discharged and referred for elective angioplasty at a future time. Exhibit A, p. 19 (CON Application).

31. The Applicants identified the following historical primary angioplasty volumes for Greenwich Hospital for FYs 2008-2011:

Table III: Greenwich Hospital Historical Primary PCI

	FY 2008	FY 2009	FY 2010	FY 2011
Greenwich Hospital	40	40	32	38

Exhibit A, p. 30 (CON Application).

32. Greenwich Hospital's angioplasty volume projections:

Table IV: Greenwich Hospital Projected Primary and Elective PCI

	FY 2012	FY 2013	FY 2014
Primary Angioplasty	38	38	38
Elective Angioplasty	53	53	53
New Referred Elective PCI	105	126	151
Total	196	217	242

Exhibit A, p. 31 (CON Application).

33. The Applicants based the projected primary angioplasty volumes on historical volumes, which have remained fairly steady for the past few years. The projected elective angioplasty volumes have been based on the historical elective angioplasty patients transferred to other facilities. Exhibit A, pp. 32-34 (CON Application).
34. The Applicants claim that half of the outpatients that have a diagnostic catheterization performed at Greenwich Hospital are transferred to other facilities for elective PCI. Exhibit H, p. 669-671 (prefiled testimony of Christopher Howes, Chief of Cardiology of Angioplasty Program at Greenwich Hospital).
35. The Applicants state that an increase in the PCI patient volume will result from the addition of New York interventional cardiologists who currently do not practice at Greenwich Hospital but have referral relationships with Greenwich Hospital medical staff and would utilize and refer elective angioplasty to Greenwich Hospital. Exhibit H, pp. 670-671, 675-676 (prefiled testimony of Christopher Howes, Chief of Cardiology of Angioplasty Program at Greenwich Hospital).
36. Although the Applicants provided letters of support from the two (2) physicians from the State of New York who state they would offer elective PCI at Greenwich Hospital if that were an option, the projected new PCI volumes are speculative and appear to be a shifting of the elective PCI patients from an area provider to Greenwich Hospital. See, Exhibit H, page 671 & 675-679 (prefiled testimony of Christopher Howes, M.D Chief of Cardiology of Angioplasty Program at Greenwich Hospital).
37. Stamford Hospital claims that elective angioplasty volumes are flat to declining in the State, with no volume growth in the Applicants' proposed service area, and therefore, there is no clear public need for the establishment of elective angioplasty program without onsite surgical back up at Greenwich Hospital. Exhibit K, p. 1 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

38. The following table illustrates the historical overall statewide PCI (primary and elective combined) discharges by provider between Federal Fiscal Years ("FFY") 2002-2011:

Table V: PCI discharges by provider, FFYs 2002-2011

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	FFY 05-07 (3-yr) % Change	FFY 09-11 (3-yr) % Change	FFY 10-11 (1-yr) % Change
Bridgeport	1,191	1,249	1,288	1,052	692	560	580	428	379	298	-47%	-30%	-21%
CT Children's								2	0		n/a	-100%	n/a
Danbury	0	0	0	0	453	409	330	326	277	292	n/a	-10%	5%
Dempsey	452	464	453	519	401	353	376	334	368	253	-32%	-24%	-31%
Greenwich	0	0	0	20	38	32	40	40	32	37	60%	-8%	16%
Hartford	1,312	1,483	1,321	1,282	1,246	1,206	1,093	1,031	1,122	1,195	-6%	16%	7%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	97	169%	31%	41%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	70	n/a	-5%	-5%
New Milford	0	0	0	0	0	6	11	11	0		n/a	-100%	n/a
Norwalk								14	57	65	n/a	364%	14%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	938	-3%	-24%	-9%
St. Mary's	0	0	0	59	297	246	251	255	291	314	317%	23%	8%
St. Raphael	715	970	924	708	680	632	595	534	523	444	-11%	-17%	-15%
St. Vincent's	1,063	1,035	1,085	1,150	1,181	1,101	1,124	958	925	509	-4%	-47%	-45%
Stamford	0	0	0	9	39	34	45	159	151	135	278%	-15%	-11%
Waterbury	0	0	0	61	347	373	325	361	361	379	511%	5%	5%
Yale	1,635	1,715	1,460	1,297	1,218	1,131	1,186	1,352	1,469	1,324	-13%	-2%	-10%
Total	7,560	8,169	7,880	7,406	7,864	7,341	7,216	7,185	7,128	6,350	-1%	-12%	-11%

Source: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07

Please note: unduplicated counts utilizing all procedure codes

*This column in OHCA's Exhibit 1, Table 2A, was mislabeled. No data from this column was relied upon to support the findings in this decision.

39. The statewide inpatient PCI volumes demonstrate the following: a five year historical decline of 1% between FY 2007-2011; a 12% overall decline between FY 2009 and 2011; and an 11% decline in statewide PCI volume between FY 2010-2011. *See*, Table V, above.

40. Stamford Hospital's PCI discharges have declined 15% between FY 2009-2011 and, therefore, Stamford Hospital has capacity to serve the needs of the community. *See*, Table V, above.

41. The Intervenor claims that discharges of residents from Greenwich Hospital's service area from Connecticut and New York hospitals show that from FY 2009 through 2011, inpatient ("I/P") cardiac catheterization and PCI volumes have decreased in the service area:

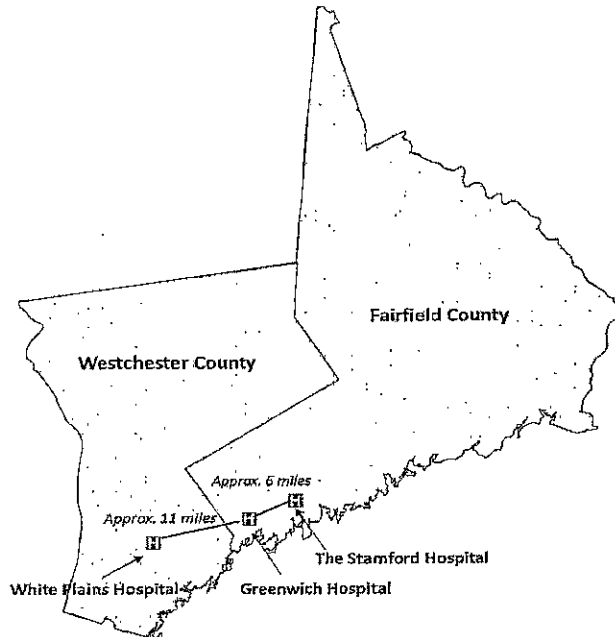
Table VI: FY 2009-2011, I/P PCI Volume in proposed Service Area

State	FY 2009	FY 2010	FY 2011
CT Service Area	598	610	429
NY Service Area	844	775	772
Total	1,442	1,385	1,201

Exhibit K, p. 8 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

42. In light of the historical elective PCI transfers from Greenwich Hospital to existing providers and the declining statewide PCI volumes, OHCA finds that the Applicants have not provided sufficient evidence to support its projected PCI utilizations.
43. A letter from White Plains Hospital states that its elective PCI program presently has capacity to serve the needs of the community and they are not aware of any backlog of cases in their service area that would indicate patients are not receiving timely care. Exhibit I, pp. 49-50 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).
44. White Plains Hospital is located approximately ten (10) miles west of Greenwich Hospital. If this application is approved, three (3) elective angioplasty programs will operate within sixteen (16) miles of each other. Exhibit K, p. 10 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

45. The map illustrates the location of Greenwich Hospital and the existing providers such as Stamford Hospital and White Plains Hospital, in Greenwich Hospital's proposed service area and their approximate distance to Greenwich Hospital:



46. There is no capital expenditure associated with this proposal. Exhibit A, p. 21(CON Application).
47. The Applicants assert that they estimate the unnecessary costs that now result and impact payers and patients total approximately \$425,000 each year. This amount is based on an average of 53 elective angioplasty cases currently transferred that could be cared for by a Greenwich Hospital's elective angioplasty program multiplied by \$8,000 (\$7,000 for the average cost of an angioplasty admission at Yale New Haven Hospital plus \$1,000 for emergency transportation). Exhibit H, p. 79 (prefiled testimony of Frank Corvino, President and CEO of Greenwich Hospital).

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

Table VII: Financial Projections Incremental to the Project

Description	FY 2013	FY 2014	FY 2015
Incremental Revenue from Operations	\$2,935	\$3,413	\$3,976
Incremental Total Operating Expense	\$2,353	\$2,744	\$3,222
Incremental Gain from Operations	\$582	\$669	\$756

Note: figures are in thousands.

Exhibit A, p. 577 (CON Application).

49. The current and three-year projected payer mix for Greenwich Hospital is as follows:

Table VIII: Current & Three-Year Projected Payer Mix

Description	Current	Year 1	Year 2	Year 3
Medicare*	40.5%	40.5%	40.5%	40.5%
Medicaid*	5.4%	5.4%	5.4%	5.4%
CHAMPUS and TriCare				
Total Government	45.9%	45.9%	45.9%	45.9%
Commercial Insurers*	48.7%	48.7%	48.7%	48.7%
Self Pay	5.4%	5.4%	5.4%	5.4%
Workers Compensation	0%	0%	0%	0%
Total Non-Government	54.1%	54.1%	54.1%	54.1%
Total Payer Mix	100%	100%	100%	100%

* Includes managed care activity.

Exhibit A, p. 40 (CON Application).

50. The Applicants assert that Greenwich Hospital's primary angioplasty services are costing Greenwich Hospital approximately \$1.78 million per year, as Greenwich Hospital has to pay Yale School of Medicine to provide 24/7 physician staffing for its existing program. The primary angioplasty program results in significant staffing costs to cover approximately 40 primary angioplasty cases treated at Greenwich Hospital each year. Utilizing the same physicians to perform elective angioplasty would be a cost-effective and efficient approach and would reduce the costs per case from the arrangement. Exhibit A, p. 20 (CON Application).

51. The Applicants claim that the proposed elective angioplasty program is cost effective as it maximizes use of the existing high-cost infrastructure of the primary angioplasty program and permits existing and available highly qualified expert physicians and staff to perform both primary and elective angioplasties for which they have been trained and are qualified to perform. In addition, as noted in the application, System-wide integration, coordination of care practices and standardization, more cost effectiveness and evidence-based care will be provided. Exhibit A, pp. 40-41 (CON Application).

52. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (General Statutes § 19a-639(a)(1)).
53. OHCA is currently in the process of establishing the statewide facilities and services plan ("the plan"). The plan was not a published document at the time of this proposal was filed; however, even if the plan is published by the time this final decision is issued, it has no bearing on the outcome of this matter, as the Applicants have not sufficiently demonstrated a clear public need for this proposal. (General Statutes § 19a-639(a)(2)).
54. There is insufficient evidence to establish that there is a clear public need for the Applicants' proposal. (General Statutes § 19a-639(a)(3)).
55. The Applicants have not satisfactorily demonstrated how this proposal will impact the financial strength of the health care system in this state. (General Statutes § 19a-639(a)(4)).
56. The Applicants have failed to satisfactorily demonstrate that their proposal would improve the accessibility of health care delivery in the region but they have satisfactorily demonstrated a potential improvement in quality and cost effectiveness. (General Statutes § 19a-639(a)(5)).
57. The Applicants have shown that there would be no change to the provision of health care services to the relevant populations and payer mix. (General Statutes § 19a-639(a)(6)).
58. The Applicants have satisfactorily identified the population to be served by their proposal but have failed to satisfactorily demonstrate that this population has a need as proposed. (General Statutes § 19a-639(a)(7)).
59. The historical elective PCI discharges in the service area do not support this proposal. (General Statutes § 19a-639(a)(8)).
60. The Applicants have failed to satisfactorily demonstrate that their proposal would not result in an unnecessary duplication of existing elective PCI services in the area. (General Statutes § 19a-639(a)(9)).

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in General Statutes § 19a-639(a) and the Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services*, 288 Conn. 790 (2008); *Steadman v. SEC*, 450 U.S. 91, 101 S.Ct. 999, *reh'g den.*, 451 U.S. 933 (1981); *Bender v. Clark*, 744 F.2d 1424 (10th Cir. 1984); *Sea Island Broadcasting Corp. v. FCC*, 627 F.2d 240, 243 (D.C. Cir. 1980).

Greenwich Hospital is a 174-bed acute care hospital located at 5 Perryridge Road in Greenwich and Yale-New Haven Hospital is an acute care hospital located at 20 York Street in New Haven. Greenwich Hospital and Yale New Haven Hospital (collectively known as "Applicants") are proposing to establish and operate an elective angioplasty program without onsite surgical backup located at Greenwich Hospital. FFs 1, 2, 8.

Currently, Greenwich Hospital, as a satellite of Yale New Haven Hospital's Yale-New Haven Heart and Vascular Center, provides cardiac catheterization and primary (emergency) angioplasty services. Greenwich Hospital does not have an on-site open heart surgery program. FF 4-6.

The Applicants argue that there is a clear public need for elective angioplasty ("elective PCI") at Greenwich Hospital and that such a program would fall within the ACCF/AHA/SCAI updated guidelines regarding elective PCI without on-site surgical backup. FFs 18, 19, 21, 22. The ACCF/AHA/SCAI guidelines now state that elective PCI might be considered in hospitals without on-site cardiac, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. FF 23.

The Applicants claim there is clear public need based on three key factors: local access, cost-effectiveness and improved quality. FF 19. Greenwich Hospital has transferred approximately 57 patients annually (between FYs 2008-2011) that required elective angioplasties to other providers over the each of the past three fiscal years. FF 30. Additionally, the Applicants claim that two new physicians (currently practicing in Westchester County, NY) will refer new angioplasty patients to Greenwich Hospital, if approved. FF 35.

Although the Applicants claim that there is need for elective PCI in the proposed service area, there are currently two providers of elective angioplasty service within its proposed service area, Stamford Hospital and White Plains Hospital. FFs 14, 44, 45. Each of the existing providers of elective angioplasty is approximately 6 and 11 miles away from Greenwich Hospital. FFs 44, 45. A letter from White Plains Hospital in Westchester County, NY, stated that its elective angioplasty program presently has capacity to serve the needs of the community and they are not aware of any backlog of cases in their service area. FF 43. Additionally, historical PCI discharge data shows that Stamford Hospital also has capacity to serve the needs of the community. FFs 37-40. Furthermore, based on OHCA's statewide hospital discharges, it's clear that since FY 2009,

the cardiac catheterization volume has declined 10% and the combined (emergent and elective) angioplasty volumes declined 12% at Connecticut providers. FFs 38-40.

The ACCF/AHA/SCAI updated guidelines state:

It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

FF 24. Regarding the proposal at hand, there is insufficient evidence to establish a void in the needs of the community for elective PCI services and that the Applicants' proposal is in the best interests of the community.

Based on the statewide decline at all Connecticut providers of cardiac catheterization and angioplasty programs, the speculative projected new cases, and the fact that there are two (2) existing providers currently providing elective PCI in Greenwich Hospital's proposed service area and that these providers have capacity to fulfill the needs of the community, OHCA finds there is access to elective angioplasty service for the residents within Greenwich Hospital's proposed service area and, further, that the Applicants failed to demonstrate and provide evidence of a clear public need for this proposal. Based upon the lack of sufficient evidence demonstrating that the Applicants' proposed project fulfills a clear public need for elective PCI, 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 of Fact and Discussion, I respectfully recommend that the Certificate of Need application of Greenwich Hospital and Yale-New Haven Hospital for the establishment of an elective angioplasty program without onsite surgical backup at Greenwich Hospital, with no associated capital expenditure, be **DENIED**.

Respectfully submitted,

Date

11/20/12

Joanne V. Yandow
Hearing Officer

JVY:swl