STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

March 21, 2014

IN THE MATTER OF:

An Application for a Certificate of Need filed Pursuant to Section 19a-638, C.G.S. by:	Notice of Final Decision Office of Health Care Access Docket Number: 12-31793-CON
Norwalk Hospital	**Establish an Elective Angioplasty Program without On-site Surgical Backup at Norwalk Hospital**

To:

Lisa M. Brady
Senior Vice President & Chief Operating Officer
Norwalk Hospital
34 Maple Street
Norwalk, CT 06856

Dear Ms. Brady:

On March 21, 2014, a decision was rendered as the finding and order of the Office of Health Care Access in the above-referenced matter. A copy of the decision is attached hereto for your information.

Kimberly R. Martone
Director of Operations

Enclosure
KRM:bac

Copy: Cristopher P. McCormack, Esq., Pullman & Comley, LLC
Stephen M. Cowherd, Esq., Jeffers Cowherd P.C.

Department of Public Health
Office of Health Care Access
Certificate of Need Application

Final Decision

Applicant: **Norwalk Hospital**
34 Maple Street, Norwalk, CT 06856

Docket Number: **12-31793-CON**

Project Title: **Establish an Elective Angioplasty Program without On-site Surgical Backup at Norwalk Hospital**

Project Description: Norwalk Hospital seeks authorization to expand its cardiovascular services to include elective percutaneous coronary intervention ("PCI") without on-site cardiac surgical backup.

Procedural History: Norwalk Hospital published notice of its intent to file the CON application in *The Hour* (Norwalk) on September 7, 8 and 9, 2012. On October 11, 2012, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from Norwalk Hospital for the above-referenced project. On January 8, 2013, OHCA deemed the application complete.

On January 17, 2013, Norwalk Hospital was notified of the date, time, and place of the public hearing. On January 19, 2013, a notice to the public announcing the hearing was published in *The Hour* (Norwalk). On February 28, 2013, OHCA received a petition from The Stamford Hospital ("Intervenor") requesting intervenor status. OHCA granted intervenor status with full rights in the matter on March 4, 2013. Thereafter, pursuant to Conn. Gen. Stat. § 19a-639a, a public hearing regarding the CON application was held on March 6, 2013.

Commissioner Jewel Mullen designated Attorney Kevin T. Hansted as the hearing officer in this matter. The hearing was conducted in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the General Statutes) and Conn. Gen. Stat. § 19a-639a. The public hearing record was closed on April 10, 2013.

On July 2, 2013 OHCA issued a Proposed Final Decision denying Norwalk Hospital's CON application. Norwalk Hospital filed Exceptions to the Proposed Decision on August 22, 2013.

Thereafter, on October 2, 2013, Commissioner Jewel Mullen opened the record and remanded this matter back to the Hearing Officer to take further evidence. Specifically, Norwalk Hospital was asked to explain why the towns of Bridgeport and Stamford were not included in its secondary service area given their corresponding patient volumes and why the use of market share in determining service area was more meaningful than overall patient volume. A second public hearing was held on November 5, 2013 and the record was closed on November 21, 2013. The Stamford Hospital was granted intervenor status with full rights for the second hearing. In rendering this decision, Deputy Commissioner Davis considered all evidence in the record.

To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc., v. S & H Computer Systems, Inc.*, 605 F.Supp. 816 (Md. Tenn. 1985).

Findings of Fact

1. Norwalk Hospital is a 366-bed not-for-profit acute care hospital located at 34 Maple Street, Norwalk, Connecticut. Ex. A, p. 11. Annual Report on the Financial Status of Connecticut's Short Term Acute Care Hospitals for Fiscal Year 2011, p. 128.

2. Norwalk Hospital has been performing primary angioplasty procedures since the inception of its program in July 2009. Ex A, p. 13.

3. Norwalk Hospital is proposing to expand its cardiac services to include an elective percutaneous coronary intervention ("PCI") program without on-site cardiac surgical backup. Ex. A, p. 12.

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. OHCA CON Final Decision, DN: 08-31210.

5. Elective angioplasty is the same procedure as primary angioplasty but is typically a scheduled procedure (within 72 hours) and is not an emergency. OHCA CON Final Decision, DN: 08-3120

6. Norwalk Hospital provided the following reasons why its cardiac program should be allowed to provide elective angioplasty:
   a. Local access;
   b. Frequency of transfers;
   c. Transfer process compromises continuity of care;
   d. Inherent complexity of patient handoffs compromises quality of care; and
   e. Cost effectiveness.

   Ex. A, pp. 14-24.

7. Norwalk Hospital defines its primary service area as Norwalk, Westport, New Canaan, Wilton, and Weston; and its secondary service area as Darien, Fairfield, Redding and Ridgefield. Ex. A, p. 27.

8. In Fiscal Year ("FY") 2012, Norwalk Hospital discharged more than two times as many patients from Bridgeport (572 discharges) and Stamford (518) than from the secondary service area towns of Darien (252), Redding (174) and Ridgefield (134).

Table 1: Norwalk Hospital Total Discharges (FY 2012)

Town	Discharges	Percent	Cumulative %
Norwalk	8,171	54.30%	54.30%
Westport	1,399	9.30%	63.60%
Wilton	954	6.34%	69.94%
New Canaan	661	4.39%	74.33%
Bridgeport	572	3.80%	78.13%
Fairfield	553	3.67%	81.80%
Stamford	518	3.44%	85.25%
Weston	316	2.10%	87.35%
New York (state)	278	1.85%	89.19%
Darien	252	1.67%	90.87%
Redding	174	1.16%	92.03%
Other State or Country	156	1.04%	93.06%
Stratford	147	0.98%	94.04%
Ridgefield	134	0.89%	94.93%
Remaining Towns/States	763	5.07%	100.00%
Total	**15,048**	**100.00%**	**100.00%**

Source: CT DPH Office of Health Care Access Acute Care Discharge Database, FY 2012

9. Although there are no providers of elective PCI services within Norwalk Hospital's stated service area, there are three existing cardiac programs within close proximity which perform, among other cardiac services, primary and elective angioplasty ("full-service cardiac program"): St. Vincent's Medical Center ("St. Vincent's"), Bridgeport Hospital, and The Stamford Hospital.
Ex. A, pp. 15 & 34.

10. St. Vincent's is located 16.9 miles from Norwalk Hospital, Bridgeport Hospital is 16.4 miles and The Stamford Hospital is 10.3 miles from Norwalk Hospital. Ex. E, p. 796.

11. Norwalk Hospital transfers more than 70% of its patients who require elective PCI to St. Vincent's. St. Vincent's will continue to serve as the primary cardiac surgery back-up for the elective PCI program if the proposal is approved.

Table 2: Norwalk Hospital Transfers: Cardiac Catheterization/Elective PCI

Cases Transferred to:	FY 11	FY 12 YTD 7/31/12	Total	% of Total
St. Vincent's Medical Center	87	103	190	71.4%
Bridgeport Hospital	21	19	40	15.0%
Stamford Hospital	15	7	22	8.3%
Yale-New Haven Hospital	3	4	7	2.6%
Hospital of St. Raphael	0	1	1	0.4%
Columbia Presbyterian	1	1	2	0.8%
Unknown or Not Available	2	2	4	1.5%
Total	**129**	**137**	**266**	**100.0%**

Source: Norwalk Hospital Transfer Log: FY 11 (10/1/10-9/30/11) and FY 12 YTD (10/1/11-7/31/12) Ex. A, p. 18.

12. There is no lack of capacity for elective angioplasty procedures to serve Norwalk Hospital's patients. Exhibit J, p 8.Intervenor's prefiled testimony of Dr. Sharon Kiely, M.D., Senior Vice-President of Medical Affairs and Chief Medical Officer for The Stamford Hospital.

13. In November 2011, the American College of Cardiology/American Heart Association/The Society for Cardiovascular Angiography and Interventions ("ACC/AHA/SCAI") updated its guideline referencing PCI without on-site surgical backup. The guideline is 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 conditions. Exhibit A, pp. 151-286.

14. According to the 2011 ACC/AHA/SCAI Guideline for Percutaneous Coronary Intervention (PCI), "It 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. 173.

15. The 2011 ACC/AHA/SCAI guideline recommends that optimally, elective PCI should be performed by operators with an acceptable annual volume (>75 total PCI procedures) at high-volume centers (>400 total PCI procedures) with on-site cardiac surgery. (*Level of Evidence: C*[1]) Exhibit A, p. 197

16. The ACC/AHA/SCAI guideline further states that it is not recommended that elective PCI be performed by low-volume operators (<75 procedures per year) at low-volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service. Exhibit A, p. 198.

17. Total (primary and elective) PCI volume for cardiac providers in Fairfield County[2] has declined from 1,617 in FY 2007 to 1,175 in FY 2012, a 27% reduction. St. Vincent's is the only center in Fairfield County currently performing more than the ACC/AHA/SCAI guideline threshold of 400 total PCI procedures annually.

Table 3: Fairfield County Total PCI Volumes

Hospital	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Bridgeport	540	555	425	364	292	237
St. Vincent's	1,051	1,048	921	904	769	621
Stamford*	26	38	252	243	229	277
Norwalk	0	0	11	54	57	40
Total	**1,617**	**1,641**	**1,609**	**1,565**	**1,347**	**1,175**

Source: Intervenor Late File 1: CHIME Inpatient/Outpatient Data Base: Report Run 2/8/13 – ICD-9 Codes 00.66, 36.03, 36.04, 36.06, 36.07, 36.09.
*Stamford Hospital received approval to establish an elective angioplasty and open heart surgery program in January 2006 under DN 04-30374-CON.

[1] The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and are ranked as LOE C.
[2] For purposes of this decision, "Fairfield County" includes St. Vincent's, Bridgeport Hospital, and The Stamford Hospital.

18. Statewide PCI volumes have declined as well, dropping from 6,891 in FY 07 to 6,038 in FY 12, a 12% decrease.

Table 4: Statewide PCI Volumes

Fiscal Year	Inpatient PCI Discharges	Outpatient PCI Discharges	Total PCI Discharges
FY 07	6,843	48	6,891
FY 08	6,709	54	6,763
FY 09	6,671	212	6,883
FY 10	6,611	232	6,843
FY 11	5,879	689	6,568
FY 12*	5,386	652	6,038

Source: Intervenor Late File 1: CHIME Inpatient/Outpatient Data Base: Report Run 2/8/13 – ICD-9 Codes 00.66, 36.03, 36.04, 36.07, 36.09.

19. Norwalk Hospital stated that distance and travel time are not primary factors with regard to the need for the proposed elective PCI program. The transfer itself is the primary clinical factor. Ex. C. p. 795

20. Norwalk Hospital claims that transferring patients who require elective PCI results in separate diagnostic catheterization and elective PCI procedures, compromising the continuity of cardiac care for its patients. Ex. A, pp. 19&20.

21. According to Dr. Michael Collins, M.D., FACC, while "transferring a patient introduces certain variables, if handled carefully, it can be done safely" and occurs regularly within/ between hospitals. Transcript of March 6, 2013 Public Hearing ("Tr."), Testimony of Dr. Michael Collins, MD, FACC, Associate Director of the Cardiac Catheterization Lab at the New York Presbyterian-Columbia University Medical Center. pp. 205 & 232.

22. Dr. Collins stated that the establishment of an additional elective PCI program will not improve the quality of cardiac care in the area, since:

    a. Transfer is not avoided for the patients who are most at-risk;
    b. Hospitals that perform elective PCI without on-site backup can suffer from a weak infrastructure because their programs can only serve one strata of cardiac patients;
    c. As lower risk procedures are performed at hospitals without on-site surgical backup, volumes decrease at the full-service hospitals, making it difficult for full-service hospitals to maintain their proficiency; and
    d. Over time, the above factors may lead to a decrease in the quality of cardiac care in the region.

    Exhibit J, p 7. Intervenor's prefiled testimony of Dr. Michael Collins, M.D., FACC, Associate Director of the Cardiac Catheterization Lab at the New York Presbyterian-Columbia University Medical Center.

23. Norwalk Hospital projects that slightly more than 200 patients would be referred by six physicians annually for primary and elective PCI in FY 14 through FY 16. For the same time period, about 150 patients per year would remain at Norwalk Hospital for the elective PCI, instead of being transferred.

Table 5: Norwalk Hospital Projected PCI Volumes

PCI Volumes by Service	FY 13*	FY 14	FY 15	FY 16
Primary Angioplasty	59	59	60	60
Elective PCI	40	147	148	150
Total	**99**	**206**	**208**	**210**
PCI Volumes by In/Out Patient	**FY 13**	**FY 14**	**FY 15**	**FY 16**
Inpatient PCI Procedures	89	186	187	189
Outpatient PCI Procedures	10	20	21	21
Total	**99**	**206**	**208**	**210**

*Assumes Elective PCI program operational as of June 1, 2013.
Ex. A, p. 45.

24. An increase in the utilization of elective angioplasty is not expected in Fairfield County. Transcript of March 6, 2013 Public Hearing ("Tr."), Testimony of Dr. Sharon Kiely, M.D., Senior Vice-President of Medical Affairs and Chief Medical Officer for The Stamford Hospital (Intervenor); p. 33.

25. The projected patient population mix for the proposed elective PCI program is based on Norwalk Hospital's existing program.

Table 6: Projected Patient Population Mix

	FY 12	FY 13	FY 14	FY 15	FY 16
Medicare	42%	39%	39%	39%	39%
Medicaid	4%	11%	11%	11%	11%
CHAMPUS & TriCare					
Total Government	**46%**	**50%**	**50%**	**50%**	**50%**
Commercial Insurers*	48%	48%	48%	48%	48%
Uninsured	6%	2%	2%	2%	2%
Workers Compensation					
Total Non-Government	**54%**	**50%**	**50%**	**50%**	**50%**
Total Payer Mix	**100%**	**100%**	**100%**	**100%**	**100%**

*Includes managed care activity
Source, FY12: CT DPH Office of Health Care Access Acute Care Discharge Database
Ex. A, p. 60.

26. Establishing an elective PCI program at Norwalk Hospital will be cost effective due to the existing infrastructure, procedures, personnel, and physicians in place as a result of the existing program. Ex., A, p. 23.

27. No additional capital costs are required to add elective PCI procedures to Norwalk Hospital's program. Ex., A, p. 23.

28. Norwalk Hospital projects incremental gains from operations in each of the first four years following the implementation of an elective PCI program.

Table 7: Financial Projections Incremental to the Proposal

Description	FY 13	FY 14	FY 15	FY 16
Incremental Revenue from Operations	$816	$2,997	$3,018	$3,059
Incremental Total Operating Expense	$204	$765	$786	$812
Incremental Gain/Loss from Operations	$612	$2,232	$2,232	$2,247

Note: Figures are in thousands
Ex., A, p. 783.

29. 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 policies and standards not yet adopted as regulations by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))

30. This CON application was deemed complete by OHCA prior to the Statewide Health Care Facilities and Services Plan becoming applicable. Therefore, OHCA has not made any findings as to the relationship between this CON application and the state wide health care facilities and services plan. (Conn. Gen. Stat. § 19a-639(a)(2))

31. Norwalk Hospital has failed to establish that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

32. OHCA is unable to conclude that Norwalk Hospital's financial projections, and volumes upon which they are based (*FF 23&28*), are reasonable and achievable, thus is unable to determine if the proposal would be financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))

33. While the proposal may be cost-effective, Norwalk Hospital has failed to satisfactorily demonstrate that the quality and accessibility of health care delivery in the region would be improved by its proposal. (Conn. Gen. Stat. § 19a-639(a)(5))

34. Norwalk Hospital has shown that there would be no change to the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))

35. Norwalk Hospital has satisfactorily identified the population to be served by its proposal, but has failed to satisfactorily demonstrate that this population has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7))

36. The historical volume of PCI discharges in the service area does not support this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))

37. Norwalk Hospital has failed to satisfactorily demonstrate that its proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 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). 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).*

Norwalk Hospital is a 366-bed acute care hospital located at 34 Maple Street, Norwalk, Connecticut. Norwalk Hospital is proposing the establishment of an elective angioplasty program without on-site surgical backup at Norwalk Hospital. *FF 1& 3.* Norwalk Hospital has been performing primary angioplasty since July 2009 and claims that clear public need for its proposal is supported by five factors: local access, frequency of transfers, claimed compromises to continuity and quality as a result of these transfers and cost-effectiveness. *FF 2 & 6.*

For purposes of defining its service area, Norwalk Hospital looks to the proportion of residents in a given community that are discharged from Norwalk Hospital as opposed to the hospitals in or near their own communities (market share). (Pre-filed testimony of Lisa M. Brady; p.7) Norwalk Hospital defines its primary service area as Norwalk, Westport, New Canaan, Wilton, and Weston; and its secondary service area as Darien, Fairfield, Redding and Ridgefield. *FF7.* Notably, Norwalk Hospital does not include the Cities of Bridgeport and Stamford in their primary or secondary service areas. However, in Fiscal Year ("FY") 2012, Norwalk Hospital discharged more than two times as many patients from Bridgeport (572 discharges) and Stamford (518) than from its secondary service area towns of Darien (252), Redding (174) and Ridgefield (134). *FF8.* While the number of discharges from Bridgeport and Stamford are minimal under a market share approach, they are substantial when viewed against discharges within Norwalk Hospital's defined secondary service area. Given this disparity, the cities of Bridgeport and Stamford cannot be ignored when considering the service area and the need for the proposed service within that service area.

While it is true that Norwalk Hospital's stated service area lacks an elective PCI program, there are three full-service cardiac programs in close proximity to Norwalk Hospital which currently provide elective PCI : St. Vincent's, Bridgeport Hospital and The Stamford Hospital located 16.9, 16.4 and 10.3 miles from Norwalk Hospital, respectively. *FF 9 & 10.* Each of these three programs have experienced periods of declining PCI volume since FY 2007. Bridgeport Hospital has seen a 56% decline in PCI volume and St. Vincent's has dropped 41%. The Stamford Hospital's volumes dropped slightly from 252 PCIs in FY 2009 to 229 in FY 2011, but increased to 277 in FY 2012. Based on the historical PCI volumes, all three of the full-service cardiac programs mentioned herein have adequate capacity to support patient demand for elective angioplasty in Fairfield County. *FF 12 & 17.*

St. Vincent's has served as the primary cardiac surgery back-up for Norwalk Hospital's PCI program. *FF 11.* Between October 1, 2010 and July 31, 2012 Norwalk Hospital transferred 266 patients for diagnostic cardiac catheterization and elective PCI; 190 (71.4%) of these patients were transferred to St. Vincent's. *FF 11.* If the proposal were approved, the majority of these

elective PCI transfers would cease. Given declining PCI utilization in Fairfield County (-27%), as well as a drop in overall statewide PCI volumes (-12%), an additional elective PCI program at Norwalk Hospital would simply shift volume away from the existing full-service programs in the area. *FF 17, 18 & 23.*

Only one of the three full service programs in close proximity to Norwalk Hospital, St. Vincent's, is performing above the optimal level of 400 PCI procedures recommended in the ACC/AHA/SCAI guidelines. St. Vincent's elective PCI program would be most significantly affected by fewer transfers resulting from an elective PCI program at Norwalk Hospital. Moreover, Norwalk Hospital's own projections, if achieved, would scarcely surpass the ACC/AHA/SCAI guideline's minimum volume threshold of 200 through FY 2016. *FF 11, FF 15-17.*

Norwalk Hospital states that distance and travel time are not primary factors with regard to the need for the proposed elective PCI program and that the transfer itself is the primary clinical factor. *FF 19.* Norwalk Hospital claims that the continuity and quality of care is compromised as a result of the current transfer process for elective PCI. *FF 6 & 20.* However, safe transfers occur regularly between hospitals and if handled carefully, can be done safely. *FF 21.*

The ACC/AHA/SCAI guideline specifically states that: "It 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." *FF 14.* Given the existing programs and significant declines in the demand for PCI, Norwalk Hospital has not provided evidence that a clear public need exists for an additional elective PCI program in the community. Adding an additional elective PCI program would result in a duplication of services and may lead to a decrease in the overall quality of cardiac care in the region. *FF 22.*

Although it may be cost-effective, due to declining PCI volumes and available capacity at existing cardiac providers in close proximity to Norwalk Hospital, OHCA is unable to conclude that Norwalk Hospital's financial projections, and the volumes upon which they are based, are reasonable and achievable, or that the project is financially feasible. *FF 23, 24, 26 & 28.* Norwalk Hospital has failed to demonstrate and provide evidence of a clear public need for this proposal.

ORDER

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of Norwalk Hospital for the establishment of an elective angioplasty program without on-site surgical backup, with no associated capital expenditure, is hereby **DENIED**.

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

3/21/14
Date

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