Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Hospital:	**Danbury Hospital**
Docket Number:	**03-30143-CON**
Project Title:	**Establish a Regional Primary and Elective Angioplasty and Open Heart Surgery Program in Danbury**
Statutory Reference:	**Sections 19a-638 & 639, Connecticut General Statutes**
Filing Date:	**February 26, 2004**
Hearing Dates:	**May 12, 2004, May 25, 2004**
Presiding Officer:	**DPH Commissioner Robert Galvin, M.D.**
Decision Date:	**July 23, 2004**
Default Date:	**Not Applicable**

Project Description: Danbury Hospital ("Hospital") proposes to establish a regional primary and elective angioplasty and open-heart surgery program, to be located at Danbury Hospital, at a capital expenditure of $5,691,866.

Nature of Proceedings: On December 16, 2003, the Office of Health Care Access ("OHCA") received the Hospital's Certificate of Need ("CON") application seeking authorization to establish a regional primary and elective angioplasty and open-heart surgery program, to be located at Danbury Hospital, at a capital expenditure of $5,691,866. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Public hearings regarding the CON Application were held on May 12, 2004 and May 25, 2004. The Hospital was notified of the date, time, and place of the hearings and notices to the public were published prior to the hearings in the *News Times* (Danbury). OHCA

Commissioner Cristine A. Vogel designated DPH Commissioner Robert Galvin, M.D. as presiding officer in this matter. The hearing is conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 and 19a-639, C.G.S.

Yale-New Haven Hospital, Bridgeport Hospital, and St. Vincent's Medical Center petitioned for party or in the alternative intervenor status with the right to present evidence and cross-examine the Hospital. The Presiding Officer granted their requests for intervenor status with the right to present evidence and cross-examine the Hospital.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Hospital and Intervenors. In rendering this decision, the presiding officer has considered the entire record of the proceeding. OHCA's authority to review, approve, modify or deny this proposal is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

Findings of Fact

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

1. Danbury Hospital is a 371-bed not-for-profit regional teaching hospital located in Danbury, Connecticut, serving over 350,000 residents of western Connecticut and eastern New York State. *(July 16, 2003, Letter of Intent, Project Description and May 17, 2004, Response to Interrogatories, page 7)*

2. The Hospital proposes to establish a regional primary and elective angioplasty[1] ("PCI") and open-heart surgery[2] ("OHS") program, to be located at Danbury

[1] Primary (Emergent) or Elective (Scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow. National data show that 14-20% of all acute myocardial infarctions or heart attacks are eligible for treatment with primary angioplasty. Primary angioplasty is clinically indicated for patients with ST segment elevation MI (STEMI) or left bundle branch block (LBBB) who need immediate intervention to open an occlusion within 90-120 minutes. Recent studies have shown that primary angioplasty can be performed in hospitals without on-site cardiac surgery because the benefit to using primary angioplasty over thrombolytics or clot busting medications outweighs the risk of having a complication that may then require cardiac surgery. Non-ST Segment elevation MI (NSTEMI or high-risk) patients consist of 80% of all MIs and are considered for angioplasty on an elective basis within 72 hours. Performance of elective angioplasty without cardiac surgery back up is not recommended by the American College of Cardiology or the American Heart Association.

[2] Open-heart surgery is a surgical intervention performed on the opened heart while the bloodstream is diverted through a heart-lung machine. Cardiac Surgery includes Coronary Artery Bypass Graft (CABG),

Hospital. The Hospital proposes to implement OHS first and perform a sufficient number of cases to validate the quality of the OHS provided. If the Cardiovascular Services Line Executive Committee is satisfied with the quality of the OHS services provided based upon outcomes and quality indicators, the Hospital will begin the provision of primary and elective PCI simulation. *(December 16, 2003 CON Application, page 28)*

3. The Hospital testified that it would take approximately three months to commence operation of the OHS program. Initiation of the PCI program would depend on physician recommendation, outcomes, and volume levels. *(Hearing Testimony)*

4. The Hospital proposes initially to dedicate one operating room at the Hospital for cardiac surgery. The Hospital anticipates that as volume and demand increases; a second operating room will be utilized for cardiac surgery. *(January 26, 2004, Responses to Completeness, page 44)*

5. The Cardiovascular Service Line Executive Oversight Committee will be responsible for internal governance of the Cardiovascular Service Line and for reviewing outcomes and action plans related to adverse events, peer review, and credentialing. This service line will report directly to the Society of Thoracic Surgery ("STS") benchmark database for normative comparisons. *(December 16, 2003 CON Application, pages 144&197)*

6. The proposed program will augment existing cardiovascular services: cardiac catheterization, intensive care and step down inpatient cardiology services, echocardiology, stress testing, cardiac rehabilitation, and cardiovascular disease prevention and health promotion programs. The Hospital also offers nuclear cardiology, cardiac MRI and PET scanning, diagnostic electrocardiography, CT exams for calcium scoring, pacemaker/automatic implantable cardiac defibrillator clinic, intra-aortic balloon pump placement, and outpatient diagnostic cardiology services. *(December 16, 2003 CON Application, page 7)*

7. The Hospital has contracted with The Cleveland Clinic Foundation ("CCF"), an Ohio nonprofit corporation, through a consulting services agreement on the development and monitoring of the training and quality assurance programs for the proposed services. CCF will provide on-site training at CCF for nurses who seek advanced education in cardio-thoracic surgery. The Hospital testified that training would take approximately 12 weeks at the CCF and the contract would be renewed for at least one additional year. *(December 16, 2003 CON Application, page 117 and Exhibit 10, pages 1034&1037 and Hearing Testimony)*

Valvuloplasty, and Valve Replacement. CABG is where a vein from the chest or leg, or a prosthesis, is grafted onto either side of a blockage in the coronary artery. This reroutes blood flow around the blockage to the heart muscle. Valvuloplasty is where a balloon tipped catheter is inserted into plaque-blocked heart valves to widen and separate them through repeated balloon inflation. A Valve Replacement is a replacement of plaque-blocked heart valves with prosthetic or tissue graft.

8. The Hospital's cardiology primary and secondary service areas consist of the following Connecticut towns:

Table 1: Danbury Hospital's Proposed CT Service Areas

	Primary	Secondary
Towns	Bethel	Bridgewater
	Brookfield	New Milford
	Danbury	Roxbury
	New Fairfield	Sherman
	Newtown	Southbury
	Redding	Woodbury
	Ridgefield	

(December 9, 2003 CON Application, page 78 and Response to Completeness received on February 23, 2004, page 6)

9. Danbury Hospital also included towns in Putnam and Dutchess County, New York in its service area. However, Sections 19a-634 and 19a-637 of the Connecticut General Statutes 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 service.

10. There is no provider of elective PCI or open-heart surgery in northern Fairfield County or Litchfield County. The nearest providers of these services to Danbury are in Bridgeport (31 miles) or New Haven (35 miles).

11. The Hospital currently has six full-time cardiologists (two invasive) and six private cardiologists (one invasive) on its cardiology staff. *(May 25, 2004, Danbury Presentation)*

12. Three cardiologists perform all of the diagnostic cardiac catheterizations[3] at the Hospital. Each cardiologist performs approximately 200 cardiac catheterizations per year. *(December 16, 2003 CON Application, page 14)*

13. The Hospital reported performing the following number of diagnostic cardiac catheterizations on residents of the Hospital's CT service areas in FYs 2001-2003:

Table 2: Danbury Hospital Historical Diagnostic Cardiac Catheterization Volume

CT Service Areas	2000	2001	2002	2003
Inpatient	328	328	263	299
Outpatient	325	323	324	327
Total	**653**	**651**	**587**	**626**

Source*: OHCA Acute Care Hospital Inpatient Discharge Database and self-reported outpatient figures.*

14. On April 21, 2004, New Milford Hospital was approved to establish diagnostic cardiac catheterization and primary angioplasty services. Upon performing 300

[3] Diagnostic Cardiac Catheterization is a diagnostic procedure in which a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to the heart to measure electrical activity, blood pressure, and locate blockages.

diagnostic cardiac catheterizations in any consecutive 12-month period, the Hospital may begin to provide primary PCI. *(Agreed Settlement under Docket Number 03-30089-CON)*

15. The Hospital based the need for the proposed angioplasty and open-heart services on the following:
    - Sufficient patient volume to assure high quality
    - Regional isolation of urban center
    - Improved local accessibility for patients
    - Reduction in mortality and morbidity
    - Improved continuity of care
    - Reduction or elimination of ambulance transfers and any repeat procedures

    (December 16, 2003 CON Application, pages 31-35 and May 25, 2004, Danbury Presentation)

16. The demographic characteristics of the Hospital's Connecticut service areas are as follows:

Table 3: Demographic Characteristics of Proposed CT Service Areas

	Population				
Service Area	**Total**	**Adults (15+)**	**15 – 44 (%)**	**45 – 64 (%)**	**65+ (%)**
Primary	179,476	139,921	43.1	24.5	10.4
Secondary	62,673	49,289	36.9	26.3	15.4
Total	242,149	189,210	41.5	25.0	11.7
Connecticut	**3,405,565**	**2,696,490**	**42.2**	**23.2**	**13.8**

Source*: Census 2000.*

17. The Hospital used 2001 Environmental Systems Research Institute (ESRI) data to project the total population in Danbury Hospital's service areas to increase by 5.5% in the primary service area and 6.1% in the secondary service area by 2006. Between 2001 and 2006, the Hospital projects the number of elderly to increase by 10% in the primary service area and 7.9% in the secondary service area. These projections could not be verified due to the claimed proprietary nature of the information. *(December 9, 2003 CON Application, pages 78 and 79).*

18. The average annual historical and projected PCI and OHS volumes for the Hospital's CT service areas for FYs 2000-2007 are as follows:

Table 4: Historical and Projected PCI Volumes for Proposed CT Service Areas

	FYs 2000 -2003		FY 2005		FY 2006		FY 2007	
CT Service Areas	**Average PCIs**	**Adult Use Rate**	**Capture Rate (%)**	**Projected PCIs**	**Capture Rate (%)**	**Projected PCIs**	**Capture Rate (%)**	**Projected PCIs**
Primary	268	1.9	75%	201	90%	241	92%	247
Secondary	133	2.7	14%	19	23%	31	33%	44
Total	**401**	**2.1**	**55%**	**220**	**68%**	**272**	**73%**	**291**

Source*: OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures, and December 9, 2003 CON Application, page 131 for capture rates).*

Table 5: Historical and Projected OHS Volumes for Proposed CT Service Areas

	FYs 2000 - 2003		FY 2005		FY 2006		FY 2007	
CT Service Areas	**Average Surgeries**	**Adult Use Rate**	**Capture Rate (%)**	**Projected Surgeries**	**Capture Rate (%)**	**Projected Surgeries**	**Capture Rate (%)**	**Projected Surgeries**
Primary	152	1.1	90%	138	96%	146	97%	147
Secondary	80	1.6	60%	48	75%	60	80%	64
Total	**232**	**1.2**	**80%**	**186**	**89%**	**206**	**91%**	**211**

Source: *OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures; and December 9, 2003 CON Application, page 131 for primary and secondary service area capture rates).*

19. In 2003, the Health Care Advisory Board Company published projections for CABG and Valve procedures that projected a 7% decline in CABG procedures and a 14% rise in valve procedures between 2003 and 2008. However since CABG procedures comprise the majority of OHS procedures, an overall decline in volume of 2% is projected in cardiac surgery. *(Prefile Testimony R. Kyle Kramer received May 17, 2004, page 4)*

20. On a statewide basis, there was a 12% decline in the number of adult open-heart surgeries and an 8% increase in PCIs from 2000 to 2003, as seen in **Attachment I**.

21. The average annual ischemic heart disease and AMI discharges and deaths in the Hospital's CT service areas for FYs 1999-2003 are as follows:

Table 6: Ischemic Heart Disease and AMI Discharges and Deaths in Proposed CT Service Areas (FYs 1999 – 2003[a])

	Discharged from CT Hospitals				Mortality	
	Ischemic Heart Disease[b]		AMI		Ischemic Heart Disease	
Service Area	**Discharges**	**Adult Rate**	**Discharges**	**Adult Rate**	**Deaths**	**Adult Rate**
Primary	859	6.1	357	2.6	200	1.4
Secondary	419	8.5	162	3.3	108	2.2
CT Service Areas	1,278	6.8	519	2.7	308	1.6
Connecticut	**-**	**8.2**	**-**	**3.2**	**-**	**1.9**

Source: *OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; CT Department of Public Health Vital Records; and Census 2000 for population figures.*

[a]Discharges were from FYs 2000 through 1st two quarters of FY 2003; Deaths were from calendar years 1999 through 2001.

[b]Includes AMI discharges.

ICD-9 codes: Ischemic Heart Disease 410-414; AMI 410.

ICD-10 codes: Ischemic Heart Disease Mortality I20–I25.

22. The average annual PCI and OHS volumes in the Hospital's CT service area by area provider for FYs 2000-2003 are as follows:

Table 7: Average Annual PCI and OHS Volumes in Proposed CT Service Areas by Provider (FYs 2000 – 2003)

	PCIs			Open-Heart Surgeries		
Hospital	**Procedures**	**Market Share (%)**	**Area Volume as Share of Total Provider Volume (%)**	**Procedures**	**Market Share (%)**	**Area Volume as Share of Total Provider Volume (%)**
Bridgeport	174	43.5	14.2	29	12.3	8.2
Hartford	29	7.2	2.3	15	6.6	1.7
John Dempsey	1	.3	.2	1	.3	.5
Saint Francis	1	.2	.01	1	.4	.01
Saint Raphael's	21	5.2	2.4	36	15.4	4.6
Saint Vincent's	28	6.9	1.8	5	2.3	5.8
Yale	130	32.5	8.3	132	56.7	13.4
Out of State	17	4.3	-	14	6.0	-
Totals	399	100.0	-	230	100.0	-

Source*: OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases.*

23. Drs. Frymus and Plestis, the proposed cardiac surgeons, would bring with them an experienced OHS team, including a heart/lung specialist, cardiac anesthesiologists, perfusionists, intensivists, physician's assistants and registered nurses. *(May 18, 2004, Prefile Testimony, page 2)*

24. Drs. Frymus and Plestis performed 377 and 648 heart surgery cases, respectively, from October 2001 to December 2003. Their recent risk adjusted CABG mortality rate in 2002 was 0.8%, as reported by the State of New York quality data. *(January 26, 2004, Responses to Completeness, page 43 and Hearing Testimony)*

25. Dr. Plestis and Frymus have developed a protocol for night, weekend, and holiday staffing to address cardiac surgical coverage. The protocol includes being at the hospital every day during the week, serving as first assistants for each other on cases, and taking emergency calls for each other. These same arrangements will be implemented at the Hospital. *(May 17, 2004, Responses to Interrogatories, page 33)*

26. The Hospital indicated that a third cardiac surgeon from the CCF might be hired for the OHS program at the Hospital if volume dictates. *(Hearing Testimony)*

27. The Hospital stated that at least two and ideally three PCI operators would have to be available to cover a 24-hour, seven day per week program at the Hospital. Given the geographic isolation of the Hospital, these operators would not be able to reasonably practice invasive cardiology at other PCI centers in Connecticut. *(January 26, 2004, Responses to Completeness, page 32)*

28. The Hospital stated that it is in the final stage of negotiations with a group of ten experienced interventional cardiologists who have agreed to dedicate two full-time interventionalists exclusively to the Hospital and to provide three interventionalists for back-up coverage of the Hospital. The group is also recruiting a third

interventional cardiologist who would be dedicated exclusively to the Hospital. The Hospital testified at the hearing that the names of the cardiologists are confidential pending CON approval. *(May 17, 2004, Responses to Interrogatories, page 10 and Hearing Testimony)*

29. Studies have shown that patients whose door-to-balloon time (the time from when a patient arrives at a hospital to the time he/she begins to undergo angioplasty) exceeded two hours had a 40-60 percent increased risk of mortality in comparison to patients with the ideal door-to-balloon time of less than one hour. *(Cannon, et.al., JAMA, 2000, "Relationship of symptom-onset-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction")*

30. The Hospital stated that if the Hospital were limited to performing primary PCI only, a minimum of 150 NSTEMI patients (an average of one every other day) would continue to be transferred every year to other facilities to undergo elective PCI. *(May 17, 2004, Responses to Interrogatories, page 22)*

31. The Hospital represented that the average door-to-balloon time for patients who present to the Hospital is over three hours, and the average symptom onset-to-balloon time for patients with ischemic heart disease evaluated at the Hospital is over five hours. This was not documented through verifiable evidence. *(December 16, 2003 CON Application, pages 46&48)*

32. Travel times to the three full-service cardiac providers most used by residents in the Hospital's proposed Connecticut service area are 58 minutes to Bridgeport Hospital, 63 minutes to Hartford Hospital and 70 minutes to Yale-New Haven Hospital. Travel minutes are only one factor in the total time to transfer a patient which also includes such things as ambulance response times, time in the Hospital's Emergency Department, and any other delays relating to patient transfer to current full-service providers. (*Yahoo Maps*)

33. The travel time evaluation study conducted in December 2003 by Parsons, et al. concluded that the "best" travel times between Danbury Hospital and SVMC and HSR ranged from 42 minutes to SVMC during the midday trip along the Primary Travel Route (I-84/Route 15) to 93 minutes during the evening peak hours along the Alternative Travel Route (I-84/Route 15) to HSR. Traffic conditions, construction activities, accidents or major incidents could significantly increase these travel times. *(December 16, 2003 CON Application, Attachment A, page 1783-1800)*

34. The Hospital stated that by maintaining the patients at a location close to home for all of their cardiac care, the cardiologists and primary care physicians treating the patients could be involved in and consult on all of the treatment provided to the patient. *(December 16, 2003 CON Application, page 66)*

35. In FY 2003, the Hospital indicated that 80 STEMI patients were transferred by ambulance to a tertiary center for PCI. *(December 16, 2003 CON Application, page 68)*

36. The Hospital stated in its Performance Improvement Plan that high-risk patients might be transferred to another cardiac referral center for their cardiac surgical care as appropriate. Patient assessment tools from STS would be used to assess risk for open-heart surgery. *(December 16, 2003 CON Application, page 205)*

37. The 2001 American College of Cardiology ("ACC") and the American Heart Association ("AHA") Guidelines for Percutaneous Coronary Intervention ("PCI") recommend that PCI be performed by higher volume operators (>75 cases/year) with advanced technical skills (e.g. subspecialty certification) at institutions with fully equipped interventional laboratories and experienced support staff. This setting will most often be in a high-volume center (>400 cases/year) associated with an on-site cardiovascular surgical program. Therefore, angioplasty is best done by high-volume operators in high-volume institutions. *(JACC, 2001, Vol. 37, No.8, page 2239)*

38. The Hospital has developed a staffing plan for the PCI services as follows:
    a) Two interventional cardiologists will be recruited to support the program
        - The first physician will have five years experience as a PCI physician, completing more then 500 individual PCI cases;
        - The second physician will have performed a minimum volume of 150 PCI cases a year;
        - They will be on-call 24 hours per day, 7 days per week to meet the needs for primary PCI;
        - At least one interventionalist will be scheduled 8 hours per day, 5 days per week for elective PCI; and
    b) 6 registered nurses and 14 cardiac technologists will staff the program;
    c) A four-person staff team will be on-call 24 hours per day, 7 days per week, and be able to mobilize to the laboratory so at least 1 team member arrives within 20 minutes, and all team members arrive within 30 minutes.

    (December 16, 2003 CON Application, pages 15&16 and January 26, 2004, Responses to Completeness, page 44)

39. Numerous studies have indicated that high volume programs and high volume operators have the best outcomes:
    - In the era of coronary stents, Medicare patients treated by high-volume (>60 PCIs) physicians and at high-volume (>160 PCIs) centers experience better outcomes following PCIs. *(McGrath, et al, "Relation Between Operator and Hospital Volume and Outcomes Following Percutaneous Coronary Interventions in the Era of the Coronary Stent", JAMA, 2000;284:3139-3144)*
    - PCI generally should not be conducted in a low-volume hospitals unless there are substantial overriding concerns about geographic or socioeconomic access. *(Jollis and Romano, MDs, "Volume-Outcome Relationship in Acute Myocardial Infarction, JAMA, 2000:284,24)*
    - Patients hospitalized for MI in New England have the highest use of B-Blocker and aspirin therapy, a low use of reperfusion therapy, and the lowest risk-adjusted 30-day mortality rate of patients nationwide. *(Krumholz, et al, "Regional variation in the treatment and outcomes of myocardial infarction: Investigating New England's advantage", American Heart Journal, August 2003)*

- Risk-adjusted mortality rates for Medicare patients undergoing CABG surgery during 1994 to 1999 were 22% higher in states without CON regulation. *(Vaughan-Sarrazin, PhD, et al, "Mortality in Medicare Beneficiaries Following CABG Surgery in States With and Without CON Regulation", JAMA, October 16, 2002, Vol 228, No. 15)*

40. A recent article by Epstein, et al. found no evidence of higher in-hospital mortality in patients undergoing PCI at medium volume (200-399 cases/year) hospitals compared with patients treated at hospitals with annual PCI volumes of 400 cases or more. Note: The study did not take into account angiographic characteristics or lesion complexity of patients, co-morbidity amongst patient populations, or whether operator volume affects outcome. *(Epstein, et al., "Hospital Percutaneous Coronary Intervention Volume and Patient Mortality, 1998 to 2000", JACC 2004; 43:1755-62 and Editorial Comment)*

41. The ACC/AHA Guidelines for CABG Surgery (1999) state the following:
    a) Studies suggest that survival after CABG is negatively affected when carried out in institutions that perform fewer than a threshold number of cases annually. Similar conclusions have been drawn regarding individual surgeon volumes.
    b) The ACC/AHA are supportive of a posture of close monitoring of institutions or individuals that perform <100 cases annually.

42. The Hospital will utilize the existing guidelines published by the ACC, AHA and STS as a basis for the development of standards for the proposed services, as specified in **Attachment II.** CCF will be consulted to define the clinical competency standards. *(December 16, 2003 CON Application, page 18)*

43. The Guidelines for Standards in Cardiac Surgery by the Advisory Council for Cardiothoracic Surgery ("ACCS") and the American College of Surgeons ("ACS") (1996) state the following:
    a) An annual volume of at least 100 to 125 open-heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume.
    b) At least 200 procedures per year as previously recommended in the 1975 report of the Inter-Society Commission on Heart Disease Resources are necessary in order for a program to function efficiently.
    c) A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the operating room.

44. The Hospital has developed a staffing plan for the OHS program as follows:
    a) Two Board-certified cardiac surgeons will be hired to work full-time;
    b) One cardiothoracic surgeon will be scheduled 8 hours per day, 5 days per week for elective surgery;
    c) Board-certified cardiac anesthesiologists and intensivists will participate in the care of the OHS patients;

d) The OHS surgical team consists of four registered nurses, 3 surgical technicians, and one cardiac operating room RN team manager
e) Mobilizing both medical and surgical support teams at any hour on any day for emergency procedures;
f) Availability of all staff to support the program 24 hours per day, 7 days per week;
g) On-call staff will be no more than 30 minutes drive time from the Hospital.

(December 16, 2003 CON Application, pages 8-10 and January 26, 2004, Responses to Completeness, page 44)

45. At least 50% of the initial core staff will have prior experience in OHS and/or PCI. Ongoing competency validation, quality review, and outcomes monitoring will be used to monitor staff effectiveness after completion of training in conjunction with CCF. *(December 16, 2003 CON Application, page 17)*

46. The Hospital projects the following number of primary and elective angioplasties and open-heart surgeries for the primary service area and Connecticut secondary service area based on its historical market share of medical cardiology DRGs of 90% in the primary service area and 17% in the secondary service area. *(December 16, 2003 CON Application, page 130 and February 23, 2004, Responses to Completeness, Revised Financial Proforma, page 14)*

Table 8: Projected CT Cardiac Volume

Service	FY 2005	FY 2006	FY 2007
Angioplasties	538	789	957
Open-heart surgeries	399	514	610

Note: Excludes pediatric population aged 0-14 years. Volume projections assume the above market share levels are achieved for interventional cardiology services.

47. The Hospital currently reports all of its cardiac catheterization laboratory data to several state and national databases for comparison of complications and utilization rates, including the National Cardiovascular Data Registry ("ACC-NCDR"). *(December 16, 2003 CON Application, page 14)*

48. Yale-New Haven Hospital, Bridgeport Hospital, and St. Vincent's Medical Center testified on the following:
a) The direct correlation between a hospital's procedural volume and its quality
b) The statewide decline in the number of OHS cases due to advancements in angioplasty
c) The flattening of PCI volume due to enhancements in medical therapies and interventional techniques
d) Excess capacity and excellent clinical outcomes (i.e. New England Advantage) at existing full-service cardiac providers
e) Proliferation of full-service cardiac programs will decrease quality and increase costs to existing programs

(May 17, 2004 Prefile Testimony of YNHH, Bridgeport Hospital, and SVMC)

49. The Hospital presented the following regarding its proposed programs:
    a) Phased in approach
    b) Historical and projected cardiac volumes
    c) CCF partnership of staff training and education and competency validation
    d) Recruitment of experienced clinicians
    e) No adverse effect on quality of care at other CT providers

    (May 25, 2004, Danbury Presentation)

Financial Feasibility of the Proposal and its Impact on the Hospital's Rates and Financial Condition
Impact of the Proposal on the Interests of Consumers and Payers of Health Care Services

50. The Applicant's proposal includes renovating 13,600 gross square foot of existing space on floors 3-10 of the Tower building at the Hospital. The renovation program includes the following:
    a) Upgrade of surgical step-down unit,
    b) Addition of an elevator to connect the surgical suite and post-PCI recovery area and CICU,
    c) Addition of a catheterization laboratory, and
    d) Renovation of support spaces for post-PCI recovery.

    (December 16, 2003, CON Application, pages 11&12)

51. The proposed new primary and elective PCI services would utilize space in the existing cardiac catheterization laboratory along with a new second single plane catheterization laboratory located adjacent to the current facility. *(December 16, 2003, CON Application, page 14&15)*

52. The proposal has a total expenditure cost of $5,691,866 which consists of the following:

Description	Cost
Construction/Renovation	$2,856,000
Medical Equipment	1,485,113
Imaging Equipment	1,300,753
Non-Medical Equipment	50,000
Total Capital Expenditure	**$5,691,866**

(December 16, 2003, CON Application, page 155)

53. The proposal will be financed from the Hospital's equity through operations of $4,691,866 and the Danbury Hospital Development Fund of $1,000,000. *(December 16, 2003 CON Application, pages 160&161)*

54. The Hospital projects a loss in operations incrementally due to the project of $4,181,000 in FY 2004. However, the Hospital projects incremental gains in operations of $4,071,000, $7,899,000, and $11,303,000 in FYs 2005, 2006, and 2007, respectively. *(February 23, 2004, Responses to Completeness, Revised Financial*

Proforma, page 14)

55. The Hospital projects gains in total hospital operations with the project of $8,601,000, $17,665,000, $22,465,000 and $26,881,000 for FYs 2004, 2005, 2006, and 2007, respectively. *(February 23, 2004, Responses to Completeness, Revised Combined Financial Proforma page/attachment Cq O-2)*

56. The Hospital's proposal will reduce the charges to payors for STEMI patients for ambulance transportation to a tertiary care facility for PCI and for any additional examinations/procedures by the receiving hospital. *(December 16, 2003 CON Application, page 68 and May 18, 2004, Prefile Testimony, page 13)*

57. The Hospital proposes to hire 16, 56, 80, and 89 Full-Time Equivalent ("FTE") positions for FYs 2004, 2005, 2006, and 2007 respectively. *(December 16, 2003, CON Application, page 53 and February 23, 2004, Responses to Completeness, Revised Financial Proforma, page 14)*

58. The Hospital's proposal will require the establishment of three new cost centers named "Cardiac Intensive Care Unit", "Cardiac Surgery OR", and "Cardiac Perfusion Services" and the units of service will be "patient days", "cases", and "cases", respectively. *(December 16, 2003, CON Application page 154)*

59. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(February 23, 2004, Responses to Completeness, Revised Financial Proforma, page 14)*

Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

The following findings are made pursuant to principles and guidelines set forth in Section 19a-637, C.G.S.:

60. There is no State Health Plan in existence at this time. *(December 16, 2003 CON Application, page 30)*

61. The Hospital has adduced evidence that this proposal is consistent with the Hospital's long-range plan. *(December 16, 2003 CON Application, page 30)*

62. The Hospital has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and applications of technology. *(December 16, 2003 CON Application, page 147)*

63. The Hospital's proposed OHS program would enhance the General Surgical residency-training program, as they would be exposed to patients with a different level of vascular surgery and the increased requirements for intensive postoperative care. The Hospital expects to participate in new research protocols regarding treatment and outcomes involving the use of primary and elective PCI and OHS. *(December 16, 2003 CON Application, page 151)*

64. The Hospital stated that the population in the Hospital's service area is growing at a rate of 1.4% per year while the number of cardiologists available to provide care to this population is decreasing. The Hospital stated that it is unable to recruit cardiologists due to its geographic isolation and lack of cardiac services. This was not documented through verifiable evidence. *(December 16, 2003 CON Application, page 152)*

65. The Hospital has sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(December 16, 2003 CON Application, page 145 and Exhibit 13)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for proposed services on a case-by-case basis. Certificate of Need ("CON") applications for cardiac services do not lend themselves to general applicability due to the variety and complexity 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 services proposed to be offered, the current utilization of services, and the financial feasibility of the proposed service. In considering this application, OHCA determined that the geographic isolation of Danbury Hospital was a significant factor in determining need.

Danbury Hospital ("Hospital") proposes to expand cardiac services at the Hospital through the implementation of a two-step process. The Hospital will initially establish an open-heart surgery ("OHS") program at the Hospital with one dedicated operating room. The Hospital testified that it would take approximately three months to commence operation of the OHS program. Initiation of the percutaneous coronary intervention ("PCI") program would depend on physician recommendation, outcomes, and volume levels. The Hospital anticipates that as volume and demand increases; a second operating room will be utilized for cardiac surgery. Based on historical market share of medical cardiology DRGs, the Hospital anticipates performing 399 OHS cases from the Hospital's Connecticut service areas in FY 2005.

The Hospital based the need for the OHS and PCI programs on regional isolation of an urban center, sufficient patient volume to assure high quality, improved local accessibility for patients, reduction in mortality and morbidity, improved continuity of care, and reduction or elimination of ambulance transfers and any repeat procedures. Recent studies have shown the benefit to using primary angioplasty over thrombolytics and the direct correlation between volume and quality. Danbury Hospital is geographically positioned to address the needs of residents in the Hospital's Connecticut service areas. There are no providers of elective PCI or OHS in the Hospital's Connecticut service areas. New Milford Hospital was recently approved to establish a diagnostic cardiac catheterization laboratory and primary PCI program, once the volume of catheterizations reaches 300 in any consecutive 12-month period. The service area for the proposed programs also includes towns in New York; however, OHCA statutorily is mandated to consider the availability, scope and need for services for the residents of Connecticut.

The Hospital's CT primary and secondary service areas have different age structures. The primary service area has a younger population with a smaller proportion of senior citizens than the secondary one and the state as a whole. The secondary service area has a higher share of elderly than Connecticut. Both of the Hospital's CT service areas have higher proportions of people aged 45–64. This age group in the near future may require more advanced cardiac services. The Hospital's CT primary service area had lower adult per capita rates for ischemic heart disease and AMI discharges and ischemic mortality than the statewide rates. The CT secondary service area had higher adult per capita

hospitalization rates for AMI and ischemic heart disease as well as ischemic mortality. Nationally, the Health Care Advisory Board projects a 7% decline in CABG procedures and a 14% rise in valve procedures from 2003 to 2008. However, since CABG procedures comprise the majority of OHS procedures, an overall decline in volume of 2% is projected in cardiac surgery in the nation. On a statewide basis, there was a 12% decline in the number of adult open-heart surgeries and an 8% increase in the number of PCIs from 2000 to 2003. There was no indication of a decline in the quality of OHS at existing providers. The existing full-service cardiac providers continue to have cardiac volumes that exceed national standards.

The Hospital performed 653, 651, 587, and 626 diagnostic cardiac catheterizations in FYs 2000, 2001, 2002, and 2003, respectively. Based on service area capture rates, OHCA estimates that the Hospital could potentially perform a minimum of 272 annual PCIs and 206 OHS cases on residents of the Hospital's Connecticut service areas in FY 2006 based on historical catheterization volume. The Hospital projects a 33% and 80% capture rate for PCIs and OHS cases, respectively, in FY 2007. Based on current medical cardiology market share levels, the Hospital projects utilization of 399, 514, and 610 OHS cases from the Hospital's Connecticut service areas for FYs 2005, 2006, and 2007. The Hospital also projects 538, 789, and 957 PCIs from the Hospital's Connecticut service areas in FYs 2005, 2006 and 2007. Based on historical service area volumes and the projected capture rates, the proposed programs would exceed minimum institutional volumes recommended by the ACC/AHA for PCI (200) and the American College of Surgeons–Advisory Council for Cardiothoracic Surgery for open-heart surgery (100–125).

Drs. Frymus and Plestis, the cardiac surgeons, are relocating from New York and are bringing with them an experienced OHS team, including a heart/lung specialist, cardiac anesthesiologists, perfusionists, intensivists, physician's assistants and registered nurses. Drs. Frymus and Plestis performed 377 and 648 heart surgery cases respectively from October 2001 to December 2003. Their recent risk adjusted CABG mortality rate in 2002 was 0.8%, as reported by the State of New York quality data. They have developed a protocol for night, weekend, and holiday staffing to address cardiac surgical coverage. The protocol includes being at the hospital every day during the week, serving as first assistants for each other on cases, and taking emergency calls for each other. These same arrangements will be implemented at the Hospital. The Hospital indicated that a third cardiac surgeon might be hired for the OHS program at the Hospital if volume dictates. The Hospital stated that at least two and ideally three PCI operators would have to be available to cover a 24-hour, seven day per week program at the Hospital. The Hospital stated that it is in the final stage of negotiations with a group of ten experienced interventional cardiologists who have agreed to dedicate two full-time interventionalists exclusively to the Hospital and to provide three interventionalists for back-up coverage of the Hospital. The group is also recruiting a third interventional cardiologist who would be dedicated exclusively to the Hospital. The Hospital testified at the hearing that the names of the cardiologists are confidential pending CON approval.

The Hospital's proposal will increase accessibility to PCI and OHS services for residents of the Connecticut service areas and reduce hospital-to-hospital transfers of the Hospital's inpatients. There is a direct relationship between the time it takes a patient to undergo primary angioplasty and the outcome. Studies have shown that patients whose door-to-balloon time (the time from when a patient arrives at a hospital's emergency room to the time he/she begins to undergo angioplasty) exceeded two hours had a 40-60 percent increased risk of mortality in comparison to patients with the ideal door-to-balloon time of less than one hour. Remoteness, road conditions, topography, travel distance and severity of winter weather conditions all impact the service area and increase travel time. Current door-to-balloon time to existing full-service cardiac providers exceeds the ideal door-to-balloon time of less than one hour. Travel minutes are only one factor in the total time to transfer a patient which also includes such things as ambulance response times, time in the Hospital's Emergency Department, and any other delays relating to patient transfer to current full-service providers. OHCA does not collect patient social security numbers or a unique patient identifier that would allow the agency to distinguish particular patients who had been transferred between acute care hospitals. The Hospital's proposal will meet ideal standards for intervention for STEMI patients. The NSTEMI or high-risk patients are considered for angioplasty on an elective basis within 72 hours. Therefore, door-to-balloon time does not apply. These are all salubrious results from improved access to patient care resulting in a reduction in morbidity and mortality.

The proposal will improve the quality of care and continuity of the Hospital's cardiac services. The Hospital has contracted with The Cleveland Clinic Foundation ("CCF"), an Ohio nonprofit corporation, through a consulting services agreement on the development and monitoring of the training and quality assurance programs for the proposed services. CCF will provide on-site training at CCF for nurses who seek advanced education in cardio-thoracic surgery. The Hospital testified that training would take approximately 12 weeks at the CCF and the contract would be renewed for at least one additional year. Both existing staff and additional specialized staffing will operate the proposed programs. The cardiologists and primary care physicians treating the residents of the area will be able to be involved in and consult on all of the treatment provided to the patient.

Finally, the CON proposal is financially feasible. The proposal has a total expenditure cost of $5,691,866, which consists of renovations to 13,600 gross square foot of existing space on floors 3-10 of the Tower building at the Hospital. The renovation program includes upgrading the surgical step-down unit, the addition of an elevator to connect the surgical suite and post-PCI recovery area and CICU, the addition of a catheterization laboratory, and renovation of support spaces for post-PCI recovery. The proposal will be financed from the Hospital's equity through operations of $4,691,866 and the Hospital's Development Fund of $1,000,000. The Hospital projects a loss in operations incremental to the project of $4,181,000 in FY 2004 due to the initial implementation of the OHS program. However, the Hospital projects incremental gains in operations of $4,071,000, $7,899,000, and $11,303,000 in FYs 2005, 2006, and 2007, respectively. The Hospital's proposal will reduce the charges to payors for STEMI patients for ambulance transport to a tertiary care facility for PCI and for any additional examinations or procedures by the

receiving hospital. The Hospital proposes to hire 16, 56, 80, and 89 Full-Time Equivalent ("FTE") positions for FYs 2004, 2005, 2006, and 2007 respectively. Despite numerous additional staff to be hired to operate the programs, the Hospital projects gains in total hospital operations with the project of $8,601,000, $17,665,000, $22,465,000 and $26,881,000 for FYs 2004, 2005, 2006, and 2007, respectively. Therefore, the CON proposal will not adversely impact the interests of consumers and payers of such services.

The Hospital's' proposed PCI and OHS programs are differentiated from other cardiac-related proposals in the following ways. First, Danbury Hospital is geographically isolated preventing appropriate access to interventional cardiac and surgical services. Danbury Hospital has developed a two-step process in establishing a full-service cardiac program. The Hospital will establish the OHS program initially and then upon meeting established benchmarks, the Hospital will commence operation of the primary and elective PCI program. This approach assures the public of the sound professional judgment behind this proposal. Secondly, the Hospital will contract with experienced and highly skilled interventional cardiologists and cardiac surgeons who will be dedicated to the Hospital's program. Even when considering recent advances in technology and trends, the Hospital has projected reasonable interventional and surgical volumes for the full-service cardiac program. Based on historical volumes and market share, OHCA concludes that the Hospital's proposed full service cardiac program will satisfy the highest quality standards. OHCA understands that volume is not the only indicator of quality; however it remains an important measure in evaluating medical technology and medical care. Finally, the Hospital has contracted with CCF for the training of existing personnel, which will provide appropriate competency and skill for all staff involved in the proposed programs. CCF's continued monitoring of the training and quality assurance programs will ensure the highest program quality. In summary, the Hospital has brought together a team of highly experienced physicians and professionals who will develop a regional solution for the delivery of advanced cardiac care in western Connecticut.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and Danbury Hospital ("Hospital") hereby stipulate and agree to the terms of settlement with respect to the establishment of a regional primary and elective angioplasty and open-heart surgery program, to be located at Danbury Hospital at a total capital expenditure of $5,691,866, as follows:

1. The Hospital's request for a CON to establish a regional primary and elective angioplasty ("PCI") and open-heart surgery ("OHS") program, to be located at Danbury Hospital at a total capital expenditure of $5,691,866, is hereby approved.

2. The Hospital shall only commence operation of the OHS program at Danbury Hospital initially. Once the number of OHS procedures exceeds 125, the Hospital may commence operation of the primary and elective angioplasty program. The primary angioplasty program shall operate 24 hours a day and seven days a week.

3. The Hospital will have two cardiac surgeons and shall identify a third cardiac surgeon to be dedicated to the program in terms of back-up OHS coverage. The surgeon must be fully credentialed and have the following qualifications:
   - Board-Certified in cardiac surgery
   - Maintains a Connecticut license and admitting privileges at the Hospital
   - Has performed OHS procedures at a cardiac surgical center that meets or exceeds the annual ACCS/ACS minimum institutional volume standard for cardiac surgery for the past 5 years
   - The third back-up cardiac surgeon will have the ability to assume responsibilities of a full-time cardiac surgeon within five (5) working days if needed

   The Hospital shall provide the Curriculum Vitae ("CV") of the third cardiac surgeon sixty (60) days prior to commencement of the OHS program. The CV shall demonstrate that the cardiac surgeon satisfies all requirements specified above. The OHS program shall not commence operation until OHCA acknowledges receipt of the CV and that it complies with this Order.

4. The Hospital will contract with two dedicated interventional cardiologists and identify a third interventional cardiologist in terms of back-up coverage for the authorized PCI program. The interventional cardiologists must be fully credentialed and have the following qualifications:
   - Board-Certified in interventional cardiology
   - Maintains a Connecticut license and admitting privileges at the Hospital
   - Meets or exceeds the annual AHA/ACC minimum operator volume standard for PCI for the past 2 years

- The third back-up interventional cardiologist will have the ability to assume responsibilities of a full-time interventional cardiologist within five (5) working days if needed

The Hospital shall provide the CVs of each cardiologist and a signed contract with the group sixty (60) days prior to commencement of the PCI program. The CVs shall demonstrate that each cardiologist satisfies all requirements specified above. The PCI program shall not commence operation until OHCA acknowledges receipt of the three CVs and that they comply with this Order.

5. The Hospital shall provide the CVs of each of the cardiac operating room nurses, Board-certified cardiac anesthesiologists, intensivists and perfusionists for the authorized OHS program sixty (60) days prior to commencement of the OHS program. Fifty percent (50)% of each of the core OR staff mentioned above must be trained in OHS prior to commencement of the OHS program. The OHS program shall not commence operation until OHCA acknowledges receipt of the CVs and that they comply with this Order.

6. The Hospital shall not exceed the approved total capital expenditure of $5,691,866. In the event the Hospital learns of potential cost increases or expects final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised CON project budget. The source of funding for the project will be Danbury Hospital's operations and owner equity.

7. Danbury Hospital shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (**Attachment III**). Data should be submitted to OHCA on a computer disk in either an excel workbook or comma-delimited text file in a format specified by OHCA. The most current version of the Connecticut Cardiac Data Registry includes, but may not be limited to, the elements listed in **Attachment III**. Data must be reported to OHCA thirty (30) calendar days following the end of the quarter. Fiscal Year quarters end December 31st, March 31st, June 30th, and September 30th. Upon receipt, OHCA will check the data's conformance to the required specifications and within ten (10) business days notify Danbury Hospital in writing of its evaluation. If OHCA finds questionable material, Danbury Hospital will have fifteen (15) business days from notification by OHCA to submit a revised dataset for evaluation. All patient-level data submitted to OHCA to satisfy this requirement will be subject to the laws and regulations of the state of Connecticut and the Office of Health Care Access regarding its collection, use and confidentiality. If the Hospital does not submit the data elements in the Connecticut Cardiac Data Registry on a quarterly basis, the programs may be terminated. In the event of such a termination, the Hospital shall file a CON for reinstitution of the programs.

8. If the Hospital does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, the Hospital shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by the Hospital. If these volumes are not met for a period of two consecutive 12-month

periods, the Hospital's OHS program shall be terminated. In the event of such a termination, the Hospital shall file a CON for reinstitution of the OHS program.

9. If the Hospital does not perform 200 PCIs within twelve months of the initiation of the PCI program, the Hospital shall submit monthly reports of PCIs arrayed by physician to OHCA until such time as these volumes are met by the Hospital. If these volumes are not met for a period of two consecutive 12-month periods, the Hospital's PCI program shall be terminated. In the event of such a termination, the Hospital shall file a CON for reinstitution of the PCI program.

10. Danbury Hospital shall participate in the Society of Thoracic Surgeons Database (STS-DB) database and the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. The Hospital shall provide OHCA quarterly data reports from STS-DB and ACC-NCDR. Data must be reported to OHCA thirty (30) calendar days subsequent to the Hospital receiving the reports from the STS and ACC. The Hospital is required to comply with the STS and ACC/AHA criteria and standards**.** If the Hospital determines not to participate in the STS-DB or ACC-NCDR, the Hospital shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in Attachment III.

11. Danbury Hospital shall provide OHCA with a copy of a dated and signed Consulting Services Agreement with The Cleveland Clinic Foundation ("CCF") sixty (60) days prior to commencement of operation of the OHS program. This contract shall be renewed annually for a period of three years.

12. OHCA and Danbury Hospital agree that this Agreed Settlement represents a final agreement between OHCA and Danbury Hospital with respect to this request. The signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Hospital with regard to Docket Number 03-30143.

13. This authorization for the OHS program shall expire on July 23, 2007. Should the Hospital's open-heart surgery program not commence operation by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.

14. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at the Hospital' expense, if the Hospital fail to comply with its terms.

Date	Duly Authorized Agent for Danbury Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on July 23, 2004.

Date	J. Robert Galvin, M.D., M.P.H. Presiding Officer

JRG:km

Recommendations for PCI Institutional and Operator Volumes at Centers With On-Site Cardiac Surgery (21, 186)

Operator Volume	Minimum Institutional Volume Institutions performing 200-400 procedures annually	Optimal Institutional Volume Institutions performing >400 procedures annually
Low (<75 procedures annually)	**Class IIb** PCI done by low-volume operators (<75) at low–volume centers (200-400).* *(Level of Evidence: C)* *Note: An institution with a volume <200 procedures/year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer the service.*	**Class IIa** PCI done by low-volume operators (<75) at high-volume centers (>400).* *(Level of Evidence: C)* *Note: Ideally, operators with annual procedure volume <75 should only work at institutions with an activity level of >600 procedures/year.*
Acceptable (≥75 procedures annually)	**Class IIa** PCI done by operators with acceptable volume (≥75) at low –volume centers (200-400). *(Level of Evidence: C)*	**Class I** PCI done by operators with acceptable volume (≥75) at high-volume centers (>400). *(Level of Evidence: B)*

*Note: Operators who perform <75 procedures/year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume ≥150 procedures/year.